

FOOD, DRUGS, AND DROODS:  
A HISTORICAL CONSIDERATION OF  
DEFINITIONS AND CATEGORIES IN AMERICAN  
FOOD AND DRUG LAW

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*This Article explores the evolution and interaction of the legal and cultural categories “food” and “drug” from the late nineteenth century to the present. The federal statutory definitions of “food” and “drug” have always been ambiguous and plastic, providing the FDA with significant regulatory flexibility. Nevertheless, the agency is not necessarily free to interpret the definitions however it chooses. “Food” and “drug” are not only product classes defined by food and drug law, but also fundamental cultural concepts. This Article demonstrates that the FDA, as well as Congress and the courts, have operated within a constraining cultural matrix that has limited their freedom to impose their preferred understandings of these categories on American society.*

*Nonetheless, history also provides ample evidence that lawmakers possess substantial power to mold the legal categories of “food” and “drug” so as to advance desired policies. One explanation for this regulatory flexibility in the face of deep-seated cultural conceptions is the indeterminate nature of the extralegal notions of “food” and “drug.” The terms, as commonly understood, embrace nebulous, overlapping, and constantly evolving realms. Moreover, the relationship between culture and law is not a one-way street with respect to these categories. Although the regulatory apparatus has always had to take into account the extralegal understandings of “food” and “drug,” the law in turn has exerted significant influence over their meaning in broader culture.*

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### INTRODUCTION

The scope of the Food and Drug Administration’s (FDA’s) power is defined primarily by the list of product categories over which the FDA has jurisdiction: food, drugs, cosmetics, devices, and biological products.<sup>1</sup> The statutory definitions of these categories delineate the outer boundaries of the arena within which the agency operates.<sup>2</sup> These definitions are also important because the FDA has different degrees of power over different categories of products. In general, the agency has greater authority over drugs, devices, and biological products than it does over food and cosmetics.<sup>3</sup> Therefore, the category to which the FDA assigns a product largely controls the shape of the regulatory regime the agency will impose on that product.

Although the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act dictate the proper classification of some types of products,<sup>4</sup> the statutory definitions are for the most part ambiguous and plastic and provide the agency with great regulatory flexibility. Courts will sometimes rein in the FDA when it interprets the definitions creatively; the Supreme Court did so, for example, with respect to the agency’s attempt in the 1990s to regulate cigarettes as

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<sup>1</sup> See Federal Food, Drug, and Cosmetic Act §§ 301–909, 21 U.S.C. §§ 301–399 (2000 & Supp. V. 2005); Public Health Service Act §§ 351, 361, 42 U.S.C. §§ 262, 264 (2000 & Supp. IV 2004).

<sup>2</sup> See Federal Food, Drug, and Cosmetic Act § 201(f)–(i), 21 U.S.C. § 321(f)–(i) (defining “food,” “drug,” “device,” and “cosmetics”); Public Health Service Act §351(i), 42 U.S.C. § 262(i) (defining “biological product”).

<sup>3</sup> Cf. Federal Food, Drug, and Cosmetic Act §§ 301–909, 21 U.S.C. §§ 301–399; Public Health Service Act § 361, 42 U.S.C. § 262.

<sup>4</sup> See, e.g., Federal Food, Drug, and Cosmetic Act § 201(f)(2), 21 U.S.C. § 321(f)(2) (stating that chewing gum is food); *id.* § 520(n), 21 U.S.C. § 360j(n) (stating that all contact lenses are devices); Public Health Services Act § 351(i), 42 U.S.C. § 262(i) (listing multiple types of products that are biological products).

medical devices.<sup>5</sup> In general, however, courts have granted the FDA considerable latitude to interpret the product definitions to vindicate “the Act’s overriding purpose to protect the public health.”<sup>6</sup> When one considers the indistinctness of, for example, the FD&C Act’s definition of “food,”<sup>7</sup> it sometimes appears that the FDA is empowered to paint on a blank canvas.

But while Congress and the courts have granted the FDA wide discretion, the agency is not necessarily free to interpret the definitions however it chooses. As Steven L. Winter has persuasively argued, the power of lawmakers effectively to frame legal categories is significantly constrained by preexisting cultural understandings of these categories.<sup>8</sup> “Food” and “drug,” the categories whose development and interaction I explore in this Article, are not only the oldest defined product classes in federal food and drug law; they are also fundamental cultural concepts.<sup>9</sup> This Article demonstrates that the FDA, as well as Congress and the courts, have operated within a cultural matrix that constrains and limits their freedom to impose their preferred understandings of these categories on American society.<sup>10</sup>

Nonetheless, my research also provides ample evidence that lawmakers have wielded substantial power to mold the legal categories of “food” and “drug” to advance desired policies.<sup>11</sup> One explanation for this regulatory flexibility in the face of deep-seated cultural conceptions is the indeterminate nature of extralegal notions of “food” and “drug.” The terms, as commonly understood, embrace nebulous, overlapping, and constantly evolving conceptual realms.<sup>12</sup> Moreover, the relationship between culture and law has not been a one-way street with respect to these categories. Although the regulatory apparatus has always had to take into account the extralegal understandings of “food” and “drug,” the law, in turn, has exerted significant influence over their meaning in broader culture.<sup>13</sup>

This Article examines the evolution of the “food” and “drug” categories from the late-nineteenth century to the present, with a focus

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<sup>5</sup> See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 131–32 (2000) (holding that Congress had precluded the FDA’s assertion of jurisdiction to regulate tobacco products as “drug delivery devices”).

<sup>6</sup> *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969); see also *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843–44 (1984) (mandating that courts defer to reasonable agency determinations of the agency’s operative statutes if the statutory language is ambiguous).

<sup>7</sup> See Federal Food, Drug, and Cosmetic Act § 201(f), 21 U.S.C. § 321(f) (defining “food” as “articles used for food or drink”).

<sup>8</sup> STEVEN L. WINTER, *A CLEARING IN THE FOREST: LAW, LIFE, AND MIND* 209–10 (2001).

<sup>9</sup> See *infra* Parts I–III.

<sup>10</sup> See *infra* Parts II–III.

<sup>11</sup> See *infra* Parts II–IV.

<sup>12</sup> See *infra* Parts II–V.

<sup>13</sup> See *infra* Parts II–III, V.

on the complex interactions between the legal and cultural notions of each category and the changing relationship of the “food” and “drug” categories to each other. Part I discusses the development of categorization theory in social-scientific and legal scholarship, with particular attention to the now-dominant “prototype” theory of human categorization. Part II considers the genesis of the “food” and “drug” definitions contained in the 1906 Federal Pure Food and Drug Act. Part II also analyzes the interpretation of these definitions in early enforcement actions brought under the 1906 Act. Part III addresses the revisions to the definitions made by the 1938 Federal Food, Drug, and Cosmetic Act and how that statute instituted a regulatory system that contributed to a growing distinction between the cultural categories of “food” and “drug.” Part III also illustrates the effects of the 1938 regime by describing how vitamin pills came to be legally categorized as “food.” Part IV explores how the 1962 establishment of mandatory premarket review of drug effectiveness further differentiated drugs from food. Finally, Part V explains how amendments to the FD&C Act in the early 1990s dramatically reshaped the “food” and “drug” categories and re-blurred the boundary between them. The Article concludes with a brief intellectual experiment, in which I ask the reader to consider the viability of a hypothetical system in which food and drugs are merged into a single category, “doods,” subject to a unified regulatory regime.

## I

### THE PROTOTYPE THEORY OF CATEGORIES

Until recently, Western thought embraced the “classical” theory of categorization, according to which categories were clearly delineated and all members of each category shared a set of “necessary and sufficient” attributes.<sup>14</sup> Starting in the 1950s, however, philosophers, psychologists, and linguists abandoned the classical theory in droves.<sup>15</sup> Perhaps the most influential figure in this exodus was psychologist Eleanor Rosch, whose studies of human categorization in the 1970s demonstrated that common categories cannot be defined by reference to a single set of necessary and sufficient attributes. Rosch also showed that people often perceive the “typicality” of category members to vary according to how many features they share with other

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<sup>14</sup> On the classical view of categorization, see GEORGE LAKOFF, *WOMEN, FIRE, AND DANGEROUS THINGS: WHAT CATEGORIES REVEAL ABOUT THE MIND* xi–xii, 5–6, 9–11 (1987); EDWARD E. SMITH & DOUGLAS L. MEDIN, *CATEGORIES AND CONCEPTS* 23 (1981); Ronald Chen & Jon Hanson, *Categorically Biased: The Influence of Knowledge Structures on Law and Legal Theory*, 77 S. CAL. L. REV. 1103, 1149–50 (2004); Lloyd K. Komatsu, *Recent Views of Conceptual Structure*, 112 PSYCHOL. BULL. 500, 502 (1992).

<sup>15</sup> For an intellectual history of the abandonment of the classical theory of categories, see LAKOFF, *supra* note 14, at 12–57; Komatsu, *supra* note 14, at 502–03.

members of the category.<sup>16</sup> The work of Rosch and others brought about a new leading (though not universally accepted) theory of categorization known as the “prototype” approach. According to this theory, the human mind constructs a category—such as “food” or “drug”—with reference to a “‘central tendency’ or average of the category members.”<sup>17</sup> The resulting fluid internal structure of a category produces different “goodness-of-example” ratings for different members.<sup>18</sup> Prototype effects also cause many categories to have “fuzzy” boundaries. Consequently, for “less typical members, there is often disagreement not only on the degree of typicality of the item, but also on whether the item belongs in another category altogether.”<sup>19</sup>

Experiments demonstrate that the construction of categories depends greatly on context.<sup>20</sup> In his influential book, *Women, Fire, and Dangerous Things*, linguist George Lakoff discussed this phenomenon from a broad cultural perspective. He argued that people organize knowledge by means of culturally dependent frameworks of background expectations he called “idealized cognitive models” (ICMs) and that “category structures and prototype effects are byproducts of that organization.”<sup>21</sup> For example, as this Article will discuss, the ICM for “drug” has shifted in the past century, and this shift has affected the typicality of particular drug products.<sup>22</sup> Whereas the prototypical drug in the late nineteenth century was a natural remedy whose safety and effectiveness were established through longstanding practice and traditional knowledge,<sup>23</sup> today’s prototypical drug is a synthetic, labo-

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<sup>16</sup> LAKOFF, *supra* note 14, at 44–45; Chen & Hanson, *supra* note 14, at 1150–53. For instance, in Rosch’s experiments, participants considered robins and sparrows to be better examples of the category “bird” than owls and eagles; in turn, participants considered owls and eagles to be better examples of “bird” than ostriches and penguins. LAKOFF, *supra* note 14, at 44–45.

<sup>17</sup> SUSAN T. FISKE & SHELLEY E. TAYLOR, *SOCIAL COGNITION* 106 (Phillip G. Zimbardo ed., McGraw-Hill 1991) (1984) (McGraw-Hill Series in Social Psychology).

<sup>18</sup> See LAKOFF, *supra* note 14, at 42–43.

<sup>19</sup> Chen & Hanson *supra* note 14, at 1153. For example, studies have shown significant disagreement over whether a stroke is a member of the category “disease” or a pumpkin is a member of the category “fruit.” See *id.* (citing Michael E. McCloskey & Sam Glucksberg, *Natural Categories: Well Defined or Fuzzy Sets?*, 6 *MEMORY & COGNITION* 468, 468–69 (1978)). Although scholars initially used Rosch’s work to argue that prototype effects inevitably produce fuzzy category boundaries, it later became clear that “goodness-of-example” ratings can also occur with respect to rigidly bound categories. LAKOFF, *supra* note 14, at 44–45.

<sup>20</sup> See Chen & Hanson, *supra* note 14, at 1153.

<sup>21</sup> LAKOFF, *supra* note 14, at 68.

<sup>22</sup> See *infra* Parts II–III.

<sup>23</sup> See CHARLES L. HUISKING, *HERBS TO HORMONES: THE EVOLUTION OF DRUGS AND CHEMICALS THAT REVOLUTIONIZED MEDICINE* 8–10 (1968) (“Before the turn of the [twentieth] century the practice of medicine still employed methods and medications carried over from Old World customs . . . Most prescriptions were of the ‘shotgun’ type. They commonly contained a dozen ingredients . . . in the pious hope that if one did not cure, another might, and none would be too harmful.”).

ratory-developed substance that has been subjected to intensive scientific research and approved by the government.<sup>24</sup>

Another source of prototype effects is a phenomenon known as “clustering,” in which a cluster of cognitive models or specific attributes combine to form a category.<sup>25</sup> Although an item may satisfy fewer than all of the models or attributes and still fall within the category, people tend to consider such an item a less typical category member than the “ideal” case, which satisfies all of the models or attributes.<sup>26</sup> Moreover, as Lakoff points out, “[w]hen the cluster of models that jointly characterize a concept diverge [in the real world], there is . . . a strong pull to view one as the most important.”<sup>27</sup> The typicality of a particular category member thus depends both on how many of the cluster of attributes it satisfies and on a culturally contingent assessment of the relative importance of these attributes.<sup>28</sup>

For instance, the cultural category “food” seems to be formed by a cluster of cognitive models, including, but not necessarily limited to, the following: things that are chewed, things that are swallowed, things used for their nutritive value, and things used for taste.<sup>29</sup> Many items generally considered to be food do not have all of these attributes. The typicality of a food seems to depend largely on how many of the models the food satisfies. Consequently, an orange, which has all four listed attributes, is probably a more typical “food” than orange juice (which is not chewed), which in turn is a more typical food than an orange lollipop (which is neither chewed nor used for nourishment). Moreover, as discussed below, the relative importance assigned to nutritive value and taste has varied over time, and this development has affected the typicality of different foods.<sup>30</sup> In short, the cultural category “food” is subject to prototype effects that make the category’s contours variable and hazy. Is parenteral nutrition, delivered intravenously, “food”?<sup>31</sup> Is chewing gum “food”?<sup>32</sup>

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<sup>24</sup> See Michelle Meadows, *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, 36 FDA CONSUMER MAGAZINE, July–Aug. 2002, [http://www.fda.gov/Fdac/features/2002/402\\_drug.html](http://www.fda.gov/Fdac/features/2002/402_drug.html) (explaining the various steps of the modern drug development and review process).

<sup>25</sup> LAKOFF, *supra* note 14, at 74.

<sup>26</sup> *Id.* at 75–76.

<sup>27</sup> *Id.* at 75.

<sup>28</sup> See *id.* at 79–84.

<sup>29</sup> See *infra* Parts II.A, III.A, IV.

<sup>30</sup> See *infra* Figure 1.

<sup>31</sup> The FDA regulates parenteral nutrition products as drugs, not food. See CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, FDA, GUIDANCE FOR INDUSTRY: FREQUENTLY ASKED QUESTIONS ABOUT MEDICAL FOODS n.2 (2007), <http://www.cfsan.fda.gov/~dms/medfguid.html> (“[P]arenteral (or intravenous) nutrient formulations . . . are regulated under existing drug law.”).

<sup>32</sup> The FDA regulates chewing gum as food. See Federal Food, Drug, and Cosmetic Act § 201(f)(2), 21 U.S.C. § 321(f)(2) (2000).

The prototype approach to category theory has recently made some inroads into legal scholarship.<sup>33</sup> Most notable is the work of Steven L. Winter, whose attack on formalist approaches to legal rules draws extensively from the prototype theorists' assault on classical categorization.<sup>34</sup> Winter contends that the entire notion of inflexible rules based on "literal" language is nonsensical.<sup>35</sup> Rules are based on categories, he explains, and "most categories . . . are flexible and functional" cultural constructs with prototype effects.<sup>36</sup> Winter describes the process by which legal rules are understood as a complex interplay of preexisting cultural categories and the rule's underlying purpose. A "rule forms its own gestalt structure or ICM consisting of the interaction of these . . . categories, and this ICM itself produces prototype effects."<sup>37</sup>

Winter focuses on how culture restrains law. He persuasively explains that "a rule risks misconstruction unless it has been fashioned from the cultural ICMs and understandings already held by those governed by the rule."<sup>38</sup> The main limitation of Winter's work is its failure to explore law's constitutive power over culture—the way that legal categories help shape cultural ones. Winter's neglect of this phenomenon is understandable when he discusses, for example, the category "animal" in a law prohibiting "live animals on the bus," because the interpretation of "animal" in such a rule would probably not significantly affect society's general understanding of the term.<sup>39</sup> However, a different approach is necessary when considering the categories "food" and "drug" in the context of federal food and drug law. The following historical examination of these categories suggests that the central legal definitions in a highly regulated field may mold cultural categories while simultaneously being constrained by them.

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<sup>33</sup> See generally Chen & Hanson, *supra* note 14, at 1150–53 (describing the prototype approach); Stuart P. Green, *Prototype Theory and the Classification of Offenses in a Revised Model Penal Code: A General Approach to the Special Part*, 4 BUFF. CRIM. L. REV. 301 (2000) (proposing to unify criminal law categorization beyond specific criminal offenses); Jay M. Feinman, *The Jurisprudence of Classification*, 41 STAN. L. REV. 661 (1989) (discussing classification problems in the fields of tort and contract law).

<sup>34</sup> See WINTER, *supra* note 8, at 206–22 (pulling together ideas presented in a series of articles that commenced in 1986).

<sup>35</sup> See *id.* at 102.

<sup>36</sup> *Id.* at 189.

<sup>37</sup> *Id.* at 103.

<sup>38</sup> *Id.* at 209.

<sup>39</sup> *Id.* at 101 (citation omitted). Winter explains how cultural notions limit the meaning of "animal" in this particular law to those animals that would tend to cause problems for other bus passengers; the law would not apply, for example, to a goldfish carried in a bag. *Id.* at 101–03.

## II

## THE 1906 PURE FOOD AND DRUGS ACT

## A. "Food" in the 1906 Act

In 1880, G. W. Wigner drafted an influential model pure food statute for the National Board of Trade that defined "food" as "every article used for food or drink by man."<sup>40</sup> Various federal bills in the 1880s and 1890s, all unsuccessful, used this rather tautological definition or a variant of it.<sup>41</sup> A few state pure food laws of the nineteenth century also echoed Wigner's "food" definition.<sup>42</sup> Other states, however, thought the definition needed further elaboration. An 1899 Act in Illinois, for example, defined "food" as "all articles, whether simple, mixed, or compound, used for food, candy, drink, or condiment, by man or domestic animals."<sup>43</sup> Congress took a similar approach when it drafted the 1906 Pure Food and Drugs Act. That statute provided: "The term 'food,' as used herein, shall include all articles used for food, drink, confectionary, or condiment by man or other animals, whether simple, mixed or compound."<sup>44</sup>

The very inclusion of a "food" definition in the statute reflected Congress's unwillingness to rely on an extralegal understanding of the category "food." The term had various meanings that did not necessarily correspond to the set of products that Congress desired to regulate. Consider the following definitions of "food" from dictionaries of the era:

What is fed upon; that which goes to support life by being received within, and assimilated by, the organism of an animal or a plant; nutriment; aliment; especially, what is eaten by animals for nourishment.<sup>45</sup>

That which is eaten or drunk for nourishment; aliment; nutriment, in the scientific sense; any substance that, being taken into

<sup>40</sup> JAMES HARVEY YOUNG, *PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906*, at 56 (1989); Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Congressional Battle for the Enactment of the First Federal Food and Drug Law in the United States*, 37 *FOOD DRUG COSM. L.J.* 310, 313 (1982). Wigner, an Englishman, almost certainly drew this language directly from the British food adulteration statute, as amended in 1875. *See* *The Sale of Food and Drugs, 1875*, 38 & 39 *Vict.*, c. 63, § 2 (Eng.) (amending the Act's definition of "food" to include "every article used for food or drink by man, other than drugs or water").

<sup>41</sup> *See* YOUNG, *supra* note 40, at 56, 98–99 (discussing failed efforts to pass the Paddock Bill during the 1890s); Litman & Litman, *supra* note 40, at 313–17 (discussing Congress's failures to approve the Hawley Bill and other proposed food and drug legislation during the 1880s and 1890s).

<sup>42</sup> In 1881, New York and New Jersey, for example, adopted the National Board of Trade model legislation. YOUNG, *supra* note 40, at 63.

<sup>43</sup> S. REP. NO. 57-3, at 10 (1901).

<sup>44</sup> Pure Food and Drugs Act, ch. 3915, § 6, 34 Stat. 768, 769 (1906) (repealed 1938).

<sup>45</sup> WEBSTER'S INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE 579 (Springfield, Mass., G. & C. Merriam & Co. 2d ed. 1890) [hereinafter WEBSTER'S 1890].



the body of animal or plant, serves, through organic action, to build up normal structure or supply the waste of tissue; nutriment; aliment, as distinguished from condiment.<sup>46</sup>

Because of prototype effects, the absence of a statutory definition would have left several critical questions unanswered. First, did the law regulate food for animals? Everyone would likely have assumed that a pure food statute addressed human food, but without clarification, it would not have been obvious whether “food” also embraced animal food. Unsurprisingly, therefore, the statutes of the period specified whether they regulated only food for man or food for man and animals.<sup>47</sup> Plant food, by contrast, was so far removed from the prototypical “food” in the context of an adulteration statute that legislators did not find it necessary to explicitly exclude fertilizers from the definition.<sup>48</sup> Second, did the statute cover beverages? Lawmakers were, of course, no less concerned about the adulteration of beverages than the adulteration of solid foods. As stated by one court, however, “The words ‘food’ and ‘drink,’ in common usage and understanding, are . . . so far from synonymous that they import a plain and fundamental distinction, as universal as language and as old as the human race.”<sup>49</sup> Pure food laws of the late nineteenth century thus all expressly defined “food” to include “drink.”<sup>50</sup>

The drafters of the 1906 Pure Food and Drug Act also deemed it necessary to state that condiments and confectionery were part of the “food” category.<sup>51</sup> As difficult as it might be for a twenty-first-century mind to imagine, substances that were used primarily for taste were *not* clearly included within the cultural category of “food” in 1906. Food was “aliment,” which Funk & Wagnalls expressly distinguished from “condiment.”<sup>52</sup> Neither of the above-quoted dictionary definitions even mentions taste; nutritive value was apparently considered the only fundamental characteristic of food.

In the late nineteenth and early twentieth centuries, American food—despite important regional, class, and ethnic differences—was generally bland, heavy, and greasy and thus not primarily associated

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<sup>46</sup> 1 A STANDARD DICTIONARY OF THE ENGLISH LANGUAGE 705 (New York, Funk & Wagnalls Co. 1st ed. 1897) [hereinafter FUNK & WAGNALLS].

<sup>47</sup> See S. REP. NO. 57-3, at 5–28 (providing an overview of each state’s food-related laws).

<sup>48</sup> Federal law still does not provide for the regulation of the sale of fertilizers; rather, regulation of fertilizers is left primarily to the states. Allison Rees Armour-Garb, Student Article, *Minimizing Human Impacts on the Global Nitrogen Cycle: Nitrogen Fertilizers and Policy in the United States*, 4 N.Y.U. ENVTL. L.J. 339, 364 (1995).

<sup>49</sup> Commonwealth v. Kebort, 61 A. 895, 896 (Pa. 1905).

<sup>50</sup> See S. REP. NO. 57-3, at 5–28.

<sup>51</sup> Pure Food Act, ch. 3915, § 6, 34 Stat. 768, 769 (1906) (repealed 1938).

<sup>52</sup> FUNK & WAGNALLS, *supra* note 46, at 705.

with taste or pleasure.<sup>53</sup> Americans used relatively few condiments, usually sweet pickles and sweet sauces.<sup>54</sup> Herb gardens were common, but herbs were grown “mainly for medicinal rather than culinary purposes.”<sup>55</sup> Exotic spices barely affected mainstream American cuisine, even as the growth of global commerce increased their availability.<sup>56</sup> Moreover, the rise of centralized industrial canning between the early 1870s and 1900 diminished the inherent flavor of the foods that Americans consumed.<sup>57</sup> One leading food historian refers to “a vague indifference to food” in Gilded Age America, “manifested in a tendency to eat and run, rather than to dine and savor.”<sup>58</sup>

Although Americans did not tend to seek sensory delight from their main dishes, desserts and other sweets were a different matter.<sup>59</sup> Americans had always craved sugar, and, after technological advances in the mid-nineteenth century enabled the mass production of confectionery, consumption of candy soared among both the upper classes (chocolates and bonbons) and the lower classes (penny candies).<sup>60</sup> Nevertheless, Americans’ sweet tooth did not cause them to closely associate “food” with taste; instead, they tended to treat confectionery as something other than food. The following exchange from a 1902 congressional hearing regarding federal pure food legislation exhibits this deeply ingrained cultural hesitation to classify candy as food.

MR. COOMBS. [Confectionery] is not food, is it?

MR. MOSES [of the National Confectioners’ Association]. Why not?

MR. RICHARDSON. I do not understand that it is food.

MR. MOSES. I suppose it would come under that general classification. It is not medicine, it is not drink; I do not know what you can call it if it is not food.

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<sup>53</sup> HARVEY A. LEVENSTEIN, *REVOLUTION AT THE TABLE: THE TRANSFORMATION OF THE AMERICAN DIET* 5–8 (1988). For discussions of regional, class, and ethnic variations, see *id.* at 10–22, 101–05 (describing the elite’s fondness for French *haute cuisine* and their views of immigrant cuisine); 1 OXFORD ENCYCLOPEDIA OF FOOD AND DRINK IN AMERICA 429 (Andrew F. Smith ed., 2004) [hereinafter OXFORD ENCYCLOPEDIA] (discussing how ethnic foods eventually changed the “bland, non-diversified” American diet); 1 *id.* at 718–19 (describing Italian-Americans’ particular resistance to Americanization of their cuisine); 2 *id.* at 471–80 (discussing American Southern cuisine).

<sup>54</sup> RICHARD J. HOOKER, *FOOD AND DRINK IN AMERICA: A HISTORY* 121 (1981); LEVENSTEIN, *supra* note 53, at 7.

<sup>55</sup> LEVENSTEIN, *supra* note 53, at 6.

<sup>56</sup> *Id.* at 5–6.

<sup>57</sup> *Id.* at 30–43; see LESLIE BRENNER, *AMERICAN APPETITE: THE COMING OF AGE OF A CUISINE* 16 (1999); 1 OXFORD ENCYCLOPEDIA, *supra* note 53, at 635–37 (describing the rise of food processing and industrialized canning in the late nineteenth century).

<sup>58</sup> LEVENSTEIN, *supra* note 53, at 8.

<sup>59</sup> See HOOKER, *supra* note 54, at 121–25, 251; LEVENSTEIN, *supra* note 53, at 6.

<sup>60</sup> See 1 OXFORD ENCYCLOPEDIA, *supra* note 53, at 176–79, 385.

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THE CHAIRMAN [Mr. Hepburn]. If you submit the question to the children they would say it is food.

....

MR. RICHARDSON. But the general acceptance is not that it is food.<sup>61</sup>

In the early 1900s, candy was considered to be distinct from “food” in law as well as in general culture. By 1902, thirty-nine states and the District of Columbia had enacted either special confectionery provisions within their pure food laws or entirely separate pure candy laws.<sup>62</sup> In many states, pure candy laws were the only pure food laws of any sort.<sup>63</sup> The separate regulation of confectionery reflected the special risk<sup>64</sup> that the adulteration of candy posed to children. It also reflected the fact that the concept of economic adulteration (the substitution of superior ingredients with inferior ingredients) was less meaningful with respect to confectionery than with respect to conventional food, because many confections were manufactured goods with no natural standards of purity, quality, or nutritional value.<sup>64</sup> The discrete legal treatment of candy may have reinforced the extralegal tendency to view confectionery as a category different from food.

Cultural developments around the turn of the twentieth century further marginalized taste as part of the concept of food. The 1890s and early 1900s were a period of great influence for pseudoscientific food faddists, who, in addition to promoting supposedly healthy eating practices, preached against “gluttony” and “gourmandizing.”<sup>65</sup> In a related development, American food advertisers tended to trumpet their products’ positive health effects rather than their taste.<sup>66</sup> In the words of one scholar: “Though healthfulness has been a recurrent theme throughout the life of American food advertising, never was it utilized as regularly, or as brazenly, as in the decades on either side of 1900.”<sup>67</sup> As shown below, in Figure 1, food advertisements between

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<sup>61</sup> *The Pure-Food Bills H.R. 3109, 12348, 9352, 276, and 4342 for Preventing the Adulteration, Misbranding and Imitation of Foods, Beverages, Candies, Drugs, and Condiments in the District of Columbia and the Territories, and for Regulating Interstate Traffic Therein, and for Other Purposes Before the H. Comm. on Interstate and Foreign Commerce, 57th Cong. 69 (1902)* [hereinafter *Pure-Food Bills Hearings*] (statement of Robert H. Moses, Member, National Confectioners’ Association).

<sup>62</sup> *Id.* at 64.

<sup>63</sup> *Id.* at 65.

<sup>64</sup> *See id.* at 65–66, 68.

<sup>65</sup> BRENNER, *supra* note 57, at 16–17; *see* 1 OXFORD ENCYCLOPEDIA, *supra* note 53, at 592–94; 2 *id.* at 2–3.

<sup>66</sup> *See* LEVENSTEIN, *supra* note 53, at 33–34.

<sup>67</sup> 1 OXFORD ENCYCLOPEDIA, *supra* note 53, at 5–7.

1895 and 1910 referred to nutrition and health far more than they referred to flavor.<sup>68</sup>

Finally, progressive reformers—in some instances the very same ones who championed the enactment of the 1906 Act<sup>69</sup>—propagated a strikingly ascetic and functional conception of food. The food reformers' program was based on the new science of nutrition, which focused on the three primary components of food—carbohydrates, fats, and proteins—and the specific physiological functions each performed.<sup>70</sup> The American agricultural chemist Wilbur Olin Atwater and other adherents of this “New Nutrition” urged the public to choose foods on the basis of their chemical composition rather than their taste or appearance.<sup>71</sup> In the words of Harvey A. Levenstein, these reformers “suffered from the Achilles’ heel of so many food reformers: bland palates and underdeveloped appreciations of the joy of eating.”<sup>72</sup> They condemned strong seasonings, which characterized immigrant cuisine, for taxing the digestive system, promoting alcoholism and other vices, and stimulating libidinous urges.<sup>73</sup> Similarly, they warned that overconsumption of sweets caused an unhealthy excess of carbohydrates in the diet,<sup>74</sup> lured children to drink, smoke, and gamble, and dangerously aroused women’s sexual passions.<sup>75</sup> The credo of the progressive-era food reformers was “eat to live rather than live to eat.”<sup>76</sup> As Leslie Brenner has observed: “Atwater’s legacy was that Americans learned to see food not as the source of pleasure, but instead merely as sustenance and fuel.”<sup>77</sup>

Congress, focusing on protecting public health and the integrity of the marketplace, obviously had no interest in excluding catsup, spices, herbs, and candy from the scope of the Pure Food and Drugs

<sup>68</sup> See *infra* note 165 and accompanying figure.

<sup>69</sup> Consider, for example, the food reformer W. O. Atwater. See *infra* notes 71–77 and accompanying text. Atwater was a pioneer in the establishment of the USDA’s Office of Experiment Stations, and the Association of American Agricultural Colleges and Experiment Stations endorsed federal pure food legislation. See *Pure-Food Bills Hearings*, *supra* note 61, at 232. Hull House founder Jane Addams, who actively attempted to reform the eating habits of the working class, also advocated the enactment of federal pure food laws. See SHANNON JACKSON, *LINES OF ACTIVITY: PERFORMANCE, HISTORIOGRAPHY, HULL-HOUSE DOMESTICITY* 124–35 (2000); LEVENSTEIN, *supra* note 53, at 105; YOUNG, *supra* note 40, at 186, 202, 233.

<sup>70</sup> See LEVENSTEIN, *supra* note 53, at 46; 2 OXFORD ENCYCLOPEDIA, *supra* note 53, at 201. Scientists also identified minerals and water as food components. LEVENSTEIN, *supra* note 53, at 46.

<sup>71</sup> BRENNER, *supra* note 57, at 17–18; LEVENSTEIN *supra* note 53, at 46–47, 72–74; see 1 OXFORD ENCYCLOPEDIA, *supra* note 53, at 678–79; 2 *id.* at 202.

<sup>72</sup> LEVENSTEIN, *supra* note 53, at 56.

<sup>73</sup> *Id.* at 5–6, 103–04; see 1 OXFORD ENCYCLOPEDIA, *supra* note 53, at 282.

<sup>74</sup> LEVENSTEIN, *supra* note 53, at 47.

<sup>75</sup> 1 OXFORD ENCYCLOPEDIA, *supra* note 53, at 178–79.

<sup>76</sup> LEVENSTEIN, *supra* note 53, at 79.

<sup>77</sup> BRENNER, *supra* note 57, at 18.

Act. To prevent any ambiguity, the drafters thus expressly included items used for condiment or confectionery in the definition of "food."<sup>78</sup> Many early FDA<sup>79</sup> enforcement actions concerned such products.<sup>80</sup> Still, as late as 1922, the agency found it necessary to clarify that the "provisions of the act relating to food, as well as the specific provisions relating to confectionery, apply to confectionery."<sup>81</sup>

Despite the multiple clarifications included within the "food" definition of the 1906 Act,<sup>82</sup> one definitional qualification is strikingly absent: the exclusion of drugs. Similar laws passed by the British Parliament in the latter part of the nineteenth century explicitly excluded "drugs" from the definition of "food."<sup>83</sup> Because the 1906 Pure Food and Drugs Act did not contain such an exception, the FDA and the courts, after some initial uncertainty discussed below, interpreted the Act to allow the dual classification of some articles as both food and drugs. By permitting this overlap, American law probably better re-

<sup>78</sup> See *supra* note 44 and accompanying text.

<sup>79</sup> The agency was not formally called the FDA until 1930, but for the sake of clarity, I will refer to it by this name throughout the Article. For a chronology of the agency's prior names, see Peter Barton Hutt, *A Historical Introduction*, 45 *FOOD DRUG COSM. L.J.* 17 (1990), reprinted in PETER BARTON HUTT, RICHARD A. MERRILL, & LEWIS A. GROSSMAN, *FOOD & DRUG LAW* 4 (3d ed. 2007).

<sup>80</sup> Twelve of the first fifty reported enforcement actions under the 1906 Act concerned products that could be characterized as condiments or confectioneries. Two such cases concerned molasses. See *1,656 Cans of Molasses Contained in 139 Cases*, Notice of Judgment No. 24 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Oct. 17, 1908); *Twenty-Six Barrels of Molasses*, Notice of Judgment No. 2 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., June 24, 1908). Three cases concerned vanilla extract. See *Heekin Spice Co.*, Notice of Judgment No. 48 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Apr. 2, 1909); *Double Extract of Vanilla, for flavoring ice creams custards, sauces, jellies, and pastry*, C.B. Woodworth Sons Co., Rochester, N.Y., Notice of Judgment No. 5 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Aug. 13, 1908); *Steinbrock & Patrick's Marvel Extract of Vanilla, 2 oz.*, Notice of Judgment No. 14 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Aug. 27, 1908). Another four cases concerned honey. See *8 Barrels "Honey"*, Notice of Judgment No. 18 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Aug. 28, 1908); *200 Cases "Honey"*, Notice of Judgment No. 19 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Aug. 28, 1908); *6 Barrels "Honey"*, Notice of Judgment No. 20 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Aug. 28, 1908); *10 Cases "Honey"*, Notice of Judgment No. 21 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Aug. 28, 1908). One case concerned pepper. See *Kitchen Queen Black Pepper*, Notice of Judgment No. 28 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Nov. 30, 1908). Another two judgments related to adulteration and misbranding of maple syrup. See *H.Y. Scanlon*, Notice of Judgment No. 47 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Mar. 13, 1909); *Four Hundred Cases and One Hundred Five-Gallon Cans of Maple Syrup*, Notice of Judgment No. 33 (Bd. of Food & Drug Inspection, U.S. Dep't of Agric., Nov. 28, 1908).

<sup>81</sup> U.S. DEP'T OF AGRIC. CIRCULAR 21, RULES AND REGULATIONS FOR THE ENFORCEMENT OF THE FOOD AND DRUGS ACT REGULATION 9 (8th rev. 1922).

<sup>82</sup> See *supra* note 44 and accompanying text.

<sup>83</sup> See, e.g., *An Act to Amend the Law [R]elating to the [S]ale of Food and Drugs*, 1899, 62 & 63 *Vict.*, c. 51, § 26 (Eng.), reprinted in 36-37 *L.R. STATUTES* 195, 202 (1899) ("'[F]ood' shall include every article used for food or drink by man, other than drugs or water.").

flected the extralegal conception of these categories than did English law.

### B. "Drug" in the 1906 Act

The 1906 Act defined "drug" to "include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals."<sup>84</sup> This definition, the product of political compromise,<sup>85</sup> both reflected and shaped the concept of "drug" in broader culture.

In 1806, Noah Webster's *A Compendious Dictionary of the English Language* defined the noun "drug" as "a medical simple."<sup>86</sup> The volume, in turn, defined a "simple" as "a single ingredient, herb, plant, drug."<sup>87</sup> In the next edition of his dictionary, published in 1828, Webster defined "drug" as follows: "The general name of substances used in medicine, sold by the druggist, and compounded by apothecaries and physicians; any substance, vegetable, animal or mineral, which is used in the composition or preparation of medicines."<sup>88</sup> This sense of "drug," as an ingredient in a fabricated "medicine," apparently dominated throughout most of the nineteenth century.<sup>89</sup> This understanding of "drug" explains the seemingly redundant use of the words "drug" and "medicine" in so many statute titles and drug catalogues of the time.<sup>90</sup> In the later years of the century, some American dictionaries moved toward treating "drug" and "medicine" as synonymous,<sup>91</sup> but the distinction persisted in others.<sup>92</sup>

At the same time, the word "drug" was often defined to encompass various substances not embraced at all by today's usage. The defi-

<sup>84</sup> Pure Food Act, ch. 3915, § 6, 34 Stat. 768, 769 (1906) (repealed 1938).

<sup>85</sup> See *infra* notes 110–25 and accompanying text.

<sup>86</sup> NOAH WEBSTER, *A COMPENDIOUS DICTIONARY OF THE ENGLISH LANGUAGE* 95 (1806).

<sup>87</sup> *Id.* at 278.

<sup>88</sup> 1 NOAH WEBSTER, *AMERICAN DICTIONARY OF THE ENGLISH LANGUAGE* 68 (1828).

<sup>89</sup> See, e.g., 3 *THE CENTURY DICTIONARY AND CYCLOPEDIA* 1781 (New York, The Century Co. 1899) ("Any vegetable, animal, or mineral substance used in the composition or preparation of medicines.").

<sup>90</sup> See, e.g., An Act to Prevent the Importation of Adulterated and Spurious Drugs and Medicines, ch. 70, 9 Stat. 237 (1848); W. H. SCHIEFFELIN & CO., *GENERAL PRICES CURRENT OF FOREIGN AND DOMESTIC DRUGS, MEDICINES, CHEMICALS, EXTRACTS, PHARMACEUTICAL PREPARATIONS, ETC.* (1881) (available at the National Library of Medicine) (same).

<sup>91</sup> FUNK & WAGNALLS, *supra* note 46, at 559 (defining drugs as "[a]ny substance used as medicine"); JAMES STORMONTH, *A DICTIONARY OF THE ENGLISH LANGUAGE* 296, 601 (1885) (defining drug as "any medicinal substance").

<sup>92</sup> WEBSTER'S 1890, *supra* note 45, at 457 ("Any animal, vegetable, or mineral substance used in the composition of medicines."); see also 2 *UNIVERSAL DICTIONARY OF THE ENGLISH LANGUAGE* 1763 (Robert Hunter & Charles Morris eds., New York, Peter Fenelon Collier 1898) ("Any substance, mineral, vegetable, or animal, used as an ingredient in physic, or in the preparation and composition of medicines; a medicinal simple.").

inition in the 1890 edition of Webster's, for example, included "any stuff used in dyeing or in chemical operations."<sup>93</sup> The reference to nontherapeutic industrial chemicals reflected the shape of nineteenth-century drug trade, in which pharmaceutical houses were not yet wholly distinct from chemical manufacturers.<sup>94</sup> In 1968, pharmaceutical executive Charles Huisking recalled:

In its original meaning, as understood at the turn of this century when I entered the drug trade, the word *drug* meant any product of the vegetable kingdom that was not chiefly used as food. It included herbs and spices, tanning agents, dyes (then chiefly of botanical origin), paint pigments, varnish gums and shellac, turpentine and rosin, various vegetable, animal and fish oils.<sup>95</sup>

Indeed, when Congress debated the 1906 Act, dealers of paints and oils voiced concern that the drug provisions would apply to them.<sup>96</sup>

Huisking's quotation makes clear that regardless of whether one used the term "drug" in its narrow (medicinal) or broad (industrial) sense, the prototypical drug at the turn of the century was an unrefined product of natural origin, probably from the vegetable kingdom. When Huisking started his career in 1898, crude drugs, which included "leaves, barks, roots, . . . fruits, seeds, oils, gums, waxes, dried insects, fossils, and even some fish and animal products,"<sup>97</sup> were "the physician's chief weapons against illness and disease"<sup>98</sup> and the principal ingredients in most of the pharmaceutical companies' formulas.<sup>99</sup> Pharmacies had a characteristic "drug store smell," emanating largely from the spices and herbs used in compounding prescriptions.<sup>100</sup> According to Huisking, even as late as 1910, "the cleverest, most forward-looking of those engaged in the drug business . . . did not realize that the day of botanical medicines was on the way out; that the founda-

<sup>93</sup> WEBSTER'S 1890, *supra* note 45, at 457; *see also* FUNK & WAGNALLS, *supra* note 46, at 559 ("[A]n ingredient of chemical compositions used in the arts . . .").

<sup>94</sup> HUISKING, *supra* note 23, at 60–61 (discussing pharmaceutical manufacturers with chemical company names); David L. Cowen, *The Role of the Pharmaceutical Industry*, in *SAFE-GUARDING THE PUBLIC: HISTORICAL ASPECTS OF MEDICINAL DRUG CONTROL* 72, 74–75 (John B. Blake ed., 1970); Owsei Temkin, *Historical Aspects of Drug Therapy*, in *DRUGS IN OUR SOCIETY* 3, 11–13 (Paul Talalay ed., 1964).

<sup>95</sup> HUISKING, *supra* note 23, at 36.

<sup>96</sup> *Alteration, Misbranding, and Imitation of Foods: Hearing on H.R. 3109 Before the S. Comm. on Manufactures*, 57th Cong. 10 (1903) (statement of Porter J. McCumber, Chairman, S. Comm. on Manufactures) ("[W]e have had from a large number of dealers in paints and oils letters in which they seem to infer that this definition of the word 'drug' will require that their paints come up to a certain standard . . .").

<sup>97</sup> HUISKING, *supra* note 23, at 36.

<sup>98</sup> *Id.* at 42.

<sup>99</sup> *See id.* ("All the brokers handled crude drugs. Every wholesale house had its crude drug department and in many cases . . . this department may well have been the very backbone of the business.").

<sup>100</sup> *DRUGSTORE MEMORIES: AMERICAN PHARMACISTS RECALL LIFE BEHIND THE COUNTER, 1824–1933*, at 137 (Glenn Sonnedecker, David L. Cowen & Gregory J. Higby, eds. 2002).

tions of chemotherapy had already been laid down.”<sup>101</sup> Only after World War I did industrially synthesized chemicals begin to dominate the pharmaceutical field in the United States.<sup>102</sup>

Because vegetable matter and, less commonly, animal matter remained the source of many drugs around 1900, the distinction between “drug” and “food” was often a blurry one, as it has been for most of human history.<sup>103</sup> Herbs were used for medicinal purposes more frequently than for culinary ones, and they were often thought to have drug-like effects even when used in cooking.<sup>104</sup> The eighth edition of the *United States Pharmacopoeia (USP)*,<sup>105</sup> an influential drug compendium prepared and periodically revised by a private standard-setting organization,<sup>106</sup> included many crude herbs, such as aloe, asafetida, belladonna, buchu, and foxglove. In addition, the volume contained numerous non-herb items that are viewed today primarily, or even exclusively, as food or food ingredients, such as corn starch, sweet orange peel, cayenne pepper, cardomon seed, caraway seed, cloves, cinnamon, and whiskey.<sup>107</sup> Similarly, the third edition of the *National Formulary (NF)*,<sup>108</sup> another compendium, included articles such as blackberry cordial, celery elixir, and orange wine.<sup>109</sup>

Wigner’s 1880 model act, discussed above, defined the word “drug” as “all medicines for internal or external use,”<sup>110</sup> and each of the unsuccessful pure food and drug bills introduced in Congress during the 1880s and 1890s used some form of this language.<sup>111</sup> When Representative Marriott Brosius introduced a revised bill in 1900, however, the definition of “drug” had contracted dramatically. Section 5 of this bill limited the meaning of the term to “all medicines and preparations recognized in the United States Pharmacopoeia for internal or external use.”<sup>112</sup> Brosius probably narrowed the definition in response to pressure from the Proprietary Association, whose members—manufacturers of over-the-counter non-*USP* patent medicines—

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<sup>101</sup> HUISKING, *supra* note 23, at 78–79.

<sup>102</sup> *See id.* at 127–28; Cowen, *supra* note 94, at 77–78.

<sup>103</sup> *See* EDWARD KREMER & GEORGE URDANG, HISTORY OF PHARMACY 3–20 (Glenn Sonnedecker rev., 3d ed. 1963) (describing pharmacy practices during ancient times).

<sup>104</sup> LEVENSTEIN, *supra* note 53, at 6, 103.

<sup>105</sup> PHARMACOPOEIA OF THE UNITED STATES OF AMERICA (8th ed. 1905).

<sup>106</sup> *See generally* LEE ANDERSON & GREGORY J. HIGBY, THE SPIRIT OF VOLUNTARISM: A LEGACY OF COMMITMENT AND CONTRIBUTION (1995) (discussing the history of the United States Pharmacopoeia and its leadership between 1820 and 1990).

<sup>107</sup> PHARMACOPOEIA, *supra* note 105.

<sup>108</sup> AM. PHARM. ASS’N, THE NATIONAL FORMULARY OF UNOFFICIAL PREPARATIONS (3d ed. 1906).

<sup>109</sup> *Id.* at 8, 11, 192

<sup>110</sup> Litman & Litman, *supra* note 40, at 313.

<sup>111</sup> *See id.* at 313, 314–317.

<sup>112</sup> H.R. 9677, 56th Cong. § 5 (1900), reprinted in *Pure-Food Bills Hearings*, *supra* note 61, at 236.



hoped to keep their products outside the scope of federal law.<sup>113</sup> The definition of “drug” that Congress eventually enacted, though not restricted solely to compendial items, included the *USP* language and also referenced the *NF*.<sup>114</sup> To this day, the definition of “drug” in the FD&C Act includes articles recognized in these compendia.<sup>115</sup>

During the late nineteenth and early twentieth centuries, the United States Pharmacopoeial Convention’s Committee of Revision selected drugs for inclusion in the *USP* based primarily, but not solely, on frequency of usage, and the Committee expressly excluded patented or otherwise protected substances and preparations.<sup>116</sup> Simple vegetable and mineral drugs still dominated the *USP VII* (1892), the edition in effect when Brosius first inserted the language.<sup>117</sup> The *USP VIII* (1905) deleted some long-used vegetable and inorganic chemical drugs, but it was still composed primarily of such simple products.<sup>118</sup> *USP VIII* was also, however, the first edition to set standards for some synthetic medicinal chemicals. This decision commenced a gradual, decades-long process during which synthetic compounds replaced many of the familiar vegetable and mineral substances in the *USP*’s pages.<sup>119</sup>

The *USP*, first published in 1820, was extremely well established by the early twentieth century, and prior laws, including the Federal Import Drug Act of 1848 and some state statutes, had explicitly incorporated its standards.<sup>120</sup> The 1906 Act’s reference to the upstart *NF* was more surprising.<sup>121</sup> The *NF*, published by the American Pharmaceutical Association (a national professional society of pharmacists)

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<sup>113</sup> See YOUNG, *supra* note 40, at 169.

<sup>114</sup> Pure Food Act, ch. 3915, § 6, 34 Stat. 768, 769 (1906) (repealed 1938) (“[T]he term ‘drug,’ as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.”); YOUNG, *supra* note 40, at 265. The 1906 Act also provided that a drug was adulterated if it was sold under a *USP* or *NF* name but differed from the standard of strength, quality, or purity set forth in the relevant compendium. Pure Food Act § 7, 34 Stat. at 769–770. Variances from these standards were allowed, however, if the manufacturer plainly stated the variance on the label. *Id.*; see YOUNG, *supra* note 40, at 265.

<sup>115</sup> Federal Food, Drug, and Cosmetic Act § 201(g)(1), 21 U.S.C. § 321(g)(1) (2000).

<sup>116</sup> See ANDERSON & HIGBY, *supra* note 106, at 162–63, 211–15.

<sup>117</sup> See *id.* at 173, 180.

<sup>118</sup> See *id.* at 214–15.

<sup>119</sup> *Id.* at 193, 208–11; see also Glenn Sonnedecker, *Drug Standards Become Official*, in THE EARLY YEARS OF FEDERAL FOOD AND DRUG CONTROL 28, 31 (Glenn Sonnedecker, ed. 1982) (Am. Inst. of the History of Pharm., Recent History and Trends of Pharmacy Series No. 1, 1982) (describing the impact of the Pure Food and Drugs Bill on the *USP* and *NF*).

<sup>120</sup> See Sonnedecker, *supra* note 119, at 28–29.

<sup>121</sup> See Glenn Sonnedecker, *The Changing Character of the National Formulary (1890–1970)*, in ONE HUNDRED YEARS OF THE NATIONAL FORMULARY: A SYMPOSIUM 21, 21–22 (Gregory J. Higby & Elaine C. Stroud, eds. 1989) (Am. Inst. of the History of Pharm., Recent History and Trends of Pharmacy Series No. 3, 1989); Sonnedecker, *supra* note 119, at 30.

did not appear until 1888, and the version issued in 1906 was only the third edition.<sup>122</sup> The purpose of the *NF* was to allow physicians to “forgo ready-made products and instead write out prescriptions that required the special skill of an educated pharmacist.”<sup>123</sup> The compendium, which included no medicinal simples, consisted mostly of quantitative formulas (some approximating secret commercial formulas) for compounded preparations containing multiple active ingredients.<sup>124</sup> The very inclusion of the *NF* in the Act’s definition of “drug” probably contributed to the evolution of the meaning of the word away from its nineteenth-century signification, “drug simple.”

Despite the Proprietary Association’s efforts, the 1906 definition of “drug” was not limited solely to articles listed in the compendia. At the urging of a group of prescription drug manufacturers and medical writers, the Act further defined “drug” as “any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.”<sup>125</sup> This “intended use” language, which was later also incorporated into the definition of “device,” survives largely intact in the FD&C Act today.<sup>126</sup> Indeed, modern food and drug law is bedeviled by the question of how the phrase “intended to” in these definitions should be construed. Regulated industries contend that intended use is established solely by representations made in labeling, advertising, and other promotion.<sup>127</sup> Conversely, the FDA maintains that it can look to the overall circumstances of distribution, foreseeable use, actual use, and internal company documents to determine a product’s intended use.<sup>128</sup> The largely unexplored origins of the “intended use” provision, and their implications for the phrase’s meaning, require further study.<sup>129</sup>

### C. “Food” and “Drug” in Early Enforcement Actions

Early notices of judgment and reported cases provide several important insights into the initial understanding of the 1906 Act’s defini-

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<sup>122</sup> See ANDERSON & HIGBY, *supra* note 106, at 151–56.

<sup>123</sup> *Id.* at 152.

<sup>124</sup> See *id.* at 155–56; Sonnedecker, *supra* note 121, at 28, 31; Sonnedecker, *supra* note 119, at 32–33.

<sup>125</sup> Pure Food Act, ch. 3915, § 6, 34 Stat. 768, 769 (1906) (repealed 1938); *Alteration, Misbranding, and Imitation of Foods: Hearing on H.R. 3109 Before the S. Comm. on Manufactures*, 57th Cong. 4 (1903).

<sup>126</sup> Federal Food, Drug, and Cosmetic Act § 201(g)(1)(B), (h)(2), 21 U.S.C. § 321(g)(1)(B), (h)(2) (2000).

<sup>127</sup> See HUTT, MERRILL & GROSSMAN, *supra* note 79, at 47 (“Throughout the Brown & Williamson litigation, the tobacco industry asserted that no court had ever found that a product was ‘intended for use’ or ‘intended to affect’ absent manufacturer claims regarding that product’s use.”); *id.* at 41–57.

<sup>128</sup> See generally *id.* at 41–57, 77–87 (discussing intended use as it relates to food, drugs, cosmetics, and the FDA’s thwarted effort to regulate tobacco).

<sup>129</sup> I intend to explore these issues in a future article.

tions of “food” and “drug.” First, courts sometimes treated the definitions as mutually exclusive.<sup>130</sup> By 1934, dual classification was so widely recognized that a provision expressly permitting it was deleted as “superfluous” from an early version of the 1938 FD&C Act.<sup>131</sup> In the years immediately following 1906, however, judges were not so certain.<sup>132</sup> Second, the FDA and the courts looked to evidence other than drug manufacturers’ explicit claims to determine the “intended use” of products. Indeed, in the years immediately following the law’s enactment, the FDA brought successful drug enforcement actions against a number of non-*USP*, non-*NF* products for which no claims of curing, mitigating, or preventing disease were made—at least none that the agency or court mentioned.<sup>133</sup> Moreover, dual use food-drug products listed in the compendia were sometimes categorized as drugs by the FDA in the apparent absence of disease claims.<sup>134</sup> In 1907, the FDA’s *Annual Report* asserted: “The policy of the Drug Laboratory is to regard as drugs all ordinary food substances . . . whenever specifically used for drug purposes. While it is not always easy to determine to which category the substance belongs, it can usually be done either by the inspection of the label or by studying the trade conditions.”<sup>135</sup>

Prior to 1938, relatively few court opinions explored the relationship between the definitions of “food” and “drug.” This dearth of

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<sup>130</sup> See, e.g., Transcript of Jury Instructions, *United States v. Four Boxes of Mulford’s Wintergreens*, (N.D.N.Y. 1914) (N.J. No. 3440), reprinted in OTIS H. GATES, U.S. DEP’T OF AGRIC., DECISIONS OF COURTS IN CASES UNDER THE FEDERAL FOOD AND DRUGS ACT 592, 593, 595 (1934) [hereinafter DECISIONS] (distinguishing between drugs and confections); Transcript of Jury Instructions, *United States v. Am. Chiclé Co.*, (D. Or. 1912) (N.J. No. 1939), reprinted in DECISIONS, *supra*, at 365 (noting that pepsin chewing gum “must be either a drug or a food”). But see, e.g., *Savage v. Scovell*, 171 F. 566 (E.D. Ky. 1908), reprinted in DECISIONS, *supra*, at 18 (ruling that “an article may be a food and a medicine both”).

<sup>131</sup> S. REP. NO. 493, at 2 (1934).

<sup>132</sup> See Transcript of Jury Instructions, *Four Boxes of Mulford’s Wintergreens*, reprinted in DECISIONS, *supra* note 130, at 592; Transcript of Jury Instructions, *Am. Chiclé Co.*, reprinted in DECISIONS, *supra* note 130, at 362.

<sup>133</sup> See, e.g., Soemnoform, Notice of Judgment No. 571 (Bd. of Food & Drug Inspection, U.S. Dep’t of Agric., Oct. 11, 1910); Blackburn’s Cascara, Wild Lemon, Castor Oil Pills, Compound, Notice of Judgment No. 32 (Bd. of Food & Drug Inspection, U.S. Dep’t of Agric., Nov. 30, 1908) (the only medicinal allusion was the name of the manufacturer: “Victory Remedy Co.”); Concentrated Oil of Pine Compound, Notice of Judgment No. 30 (Bd. of Food & Drug Inspection, U.S. Dep’t of Agric., Nov. 28, 1908) (the only allusion to medicinal use in the labeling was the name of the company: “The Globe Pharmaceutical Co.”).

<sup>134</sup> See, e.g., Gum Asafetida (*Fœtida Ferula*) 1 pound, Notice of Judgment No. 583 (Bd. of Food & Drug Inspection, U.S. Dep’t of Agric., Aug. 27, 1908); 25 Boxes of 12 Bottles of Bitters, Notice of Judgment No. 483 (Bd. of Food & Drug Inspection, U.S. Dep’t of Agric., June 25, 1910).

<sup>135</sup> Peter Barton Hutt, *Government Regulation of Health Claims in Food Labeling and Advertising*, 41 FOOD DRUG COSM. L.J. 3, 5 (1986) (quoting 1907 BUREAU OF CHEMISTRY ANNUAL REPORT 13–14) (emphasis added) (citation omitted).

analysis probably reflects the fact that, from a practical perspective, the categorization of a product was rarely significant under the 1906 Act; the Act subjected food and drugs to similar, overlapping regimes of postmarket adulteration and misbranding enforcement.<sup>136</sup> In *United States v. Four Boxes of Mulford's Wintergreens*,<sup>137</sup> however, the definitional question was critical, and the opinion thus contains one of the richest early discussions of how to classify a product on the food–drug spectrum.

In *Mulford's*, the United States seized wintergreen candies in a cigar store, alleging they were adulterated because they contained talc.<sup>138</sup> Under the 1906 Act, the presence of talc automatically rendered confectionery—but not drugs—adulterated.<sup>139</sup> Thus, in the condemnation proceeding before the district court, the claimant-manufacturer contended that its product was a drug rather than a confectionery. In court, the claimant asserted that wintergreen oil “aided digestion.”<sup>140</sup> Apparently, however, it had not made this claim or any other disease-related claim in labeling or advertising.<sup>141</sup> Significantly, the judge did not hold as a matter of law that the absence of disease claims automatically rendered the mints a confectionary rather than a drug. Instead, he held that the classification of the wintergreens was a question for the jury.<sup>142</sup>

In the jury instructions, the judge prohibited dual classification, telling the jury members that if they found the article was a drug “you should find that it is not a confection.”<sup>143</sup> The judge implied that he thought the weight of the evidence tended to show that the mints were a confectionary product instead of a drug,<sup>144</sup> but he did not focus on the absence of disease claims. Instead, he intimated that the categorization of the mints depended primarily on the overall circumstances of their distribution and the inherent characteristics of the

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<sup>136</sup> See Pure Food Act, ch. 3915, §§ 7–8, 34 Stat. 768, 769–71 (1906) (repealed 1938).

<sup>137</sup> Transcript of Jury Instructions, *Four Boxes of Mulford's Wintergreens*, reprinted in DECISIONS, *supra* note 130, at 592.

<sup>138</sup> *Id.* at 592–93.

<sup>139</sup> Pure Food Act, ch. 3915, § 7, 34 Stat. at 769–70.

<sup>140</sup> Transcript of Jury Instructions, *Four Boxes of Mulford's Wintergreens*, reprinted in DECISIONS, *supra* note 130, at 594. Oil of wintergreen itself was a USP substance, but the judge noted, “Of course as to these wintergreens, there is no pretense here that the particular composition is recognized in the [USP].” *Id.*

<sup>141</sup> See *id.* at 597–98 (noting that the manufacturer consistently referred to the wintergreens as “confectionaries” only).

<sup>142</sup> *Id.* at 598 (“[Were the wintergreens] intended to be used . . . as a confection or as a drug or a medicine? That is . . . for you[, the jury,] to decide.”).

<sup>143</sup> *Id.* at 595; see also Transcript of Jury Instructions, *United States v. Am. Chicle Co.*, (D. Or. 1912) (N.J. No. 1939), reprinted in DECISIONS, *supra* note 130, at 365 (stating that pepsin chewing gum “must be either a drug or a food”).

<sup>144</sup> See, e.g., Transcript of Jury Instructions, *Four Boxes of Mulford's Wintergreens*, reprinted in DECISIONS, *supra* note 130, at 595 (noting that one would need to eat five boxes of the wintergreens to ingest a single medicinal dose of oil of wintergreen).

product itself.<sup>145</sup> With respect to the first factor, the judge observed: “[I]f you should purchase a stick of peppermint candy in the candy shop . . . you would hardly say that the stick of peppermint candy was a drug.”<sup>146</sup> With respect to the second factor, the judge conceded that a candy intended to treat disease could be classified a drug even if it contained “but a trifle of . . . essence or oil in it,”<sup>147</sup> but he suggested that the tiny amount of wintergreen oil in Mulford’s mints was important evidence that they were not, in fact, intended for use against disease.<sup>148</sup> Finally, the judge pointed to the fact that the claimant had stamped “Confectionery in tin” on shipping bills as possible evidence of Mulford’s true intent.<sup>149</sup> The jury ultimately determined that the wintergreens were adulterated confectioneries.<sup>150</sup>

Labeling and promotional claims did provide important evidence of intent in other cases decided soon after the passage of the 1906 Act. Indeed, courts repeatedly classified food-like items as drugs solely because of such claims.<sup>151</sup> For example, the Fifth Circuit did not hesitate to declare Robinson Springs Water a drug based on the disease claims on its label.<sup>152</sup> “[F]alse and fraudulent representations may be made with respect to the curative affect of substances’ . . . and when so made of water it seems to us it would be trifling to say that water ordinarily is not a drug in the true meaning of the word.”<sup>153</sup> Interestingly, however, some cases implied that even articles bearing disease claims could sometimes be classified as “food” and not “drugs.” For example, one court left it up to the jury to decide whether Beeman’s Pepsin Chewing Gum, expressly labeled “A delicious remedy for all forms of indigestion,”<sup>154</sup> was a food or a drug.<sup>155</sup> Overall, courts were flexible and pragmatic regarding the role of la-

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<sup>145</sup> *Id.* at 595, 597–98.

<sup>146</sup> *Id.* at 593.

<sup>147</sup> *Id.*

<sup>148</sup> *Id.* at 594–95.

<sup>149</sup> *Id.* at 598.

<sup>150</sup> *Id.* at 592 (“Verdict in favor of the United States.”).

<sup>151</sup> See *infra* note 153 and cases cited therein.

<sup>152</sup> See *Bradley v. United States*, 264 F. 79, 82 (5th Cir. 1920).

<sup>153</sup> *Id.* at 81–82 (quoting *Seven Cases v. United States*, 239 U.S. 510, 517 (1916)); see also *Eames’ Tonic Headache Wafers*, Notice of Judgment No. 449 (Bd. of Food & Drug Inspection, U.S. Dep’t of Agric., June 28, 1910) (crackers advertised as treatment for headaches); *Cafe-Coca Compound*, Notice of Judgment No. 235 (Bd. of Food & Drug Inspection, U.S. Dep’t of Agric., Mar. 28, 1910) (syrup containing “healthful oils”); 10 *Cases of Baird-Daniel’s Co.’s Distilled Buchu Gin*, Notice of Judgment No. 134 (Bd. of Food & Drug Inspection, U.S. Dep’t of Agric., Feb. 8, 1910) (gin advertised as “without an equal for kidney and bladder troubles”).

<sup>154</sup> Transcript of Jury Instructions, *United States v. Am. Chicle Co.*, (D. Or. 1912) (N.J. No. 1939), reprinted in *DECISIONS*, *supra* note 130, at 362.

<sup>155</sup> *Id.* at 366 (“I think it must be a question of fact for you to determine from this testimony whether this is a food or a drug.”).

beling and promotional claims in product categorization under the 1906 Act.

### III

#### THE 1938 FOOD, DRUG, AND COSMETIC ACT

##### A. "Food" and "Drug" in the 1938 Act

The definitions of "food" and "drug" in the 1934 edition of Webster's *New International Dictionary*, the first major revision since 1909, reflected the impact of almost three decades of federal regulation as well as scientific and cultural changes. Webster's definition of "food" still focused on its nutritive qualities, but, for the first time, the dictionary also alluded to its sensory characteristics.<sup>156</sup> The definition stated that "texture, consistency, digestibility, palatability, etc. . . . also materially affect the value of food substances."<sup>157</sup> Notably, Webster's further referred to taste by paraphrasing the *legal* definition of "food": "As used in laws prohibiting adulteration, etc., *food* is generally held to mean any article used as food or drink by man, whether simple, mixed, or compound, *including food adjuncts such as condiments, spice, etc.*, and often excluding drugs and natural water."<sup>158</sup> The 1934 Webster's dictionary embraced the legal meaning of "drug" even more directly.<sup>159</sup> After briefly defining a drug as "[a]ny substance used as a medicine, or in making medicines," Webster's quoted the entire definition of "drug" from the 1906 Pure Food and Drugs Act.<sup>160</sup> The dictionary demoted the definition "any stuff used in dyeing or in chemical operations" to an obsolete usage, a decision which may also reflect the influence of the law on the common understanding of the word "drug."<sup>161</sup> In short, by the time Congress began drafting what would become the 1938 FD&C Act (1938 Act), the everyday meanings of both "food" and "drug" seem to have shifted significantly.

The 1938 Act contained the definition of "food" that remains in effect today: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."<sup>162</sup> Congress expressly listed chewing gum so as to "elimi-

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<sup>156</sup> See WEBSTER'S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE 982 (2d ed. 1934) [hereinafter WEBSTER'S 1934].

<sup>157</sup> *Id.*

<sup>158</sup> *Id.* (second emphasis added).

<sup>159</sup> See *id.* at 791.

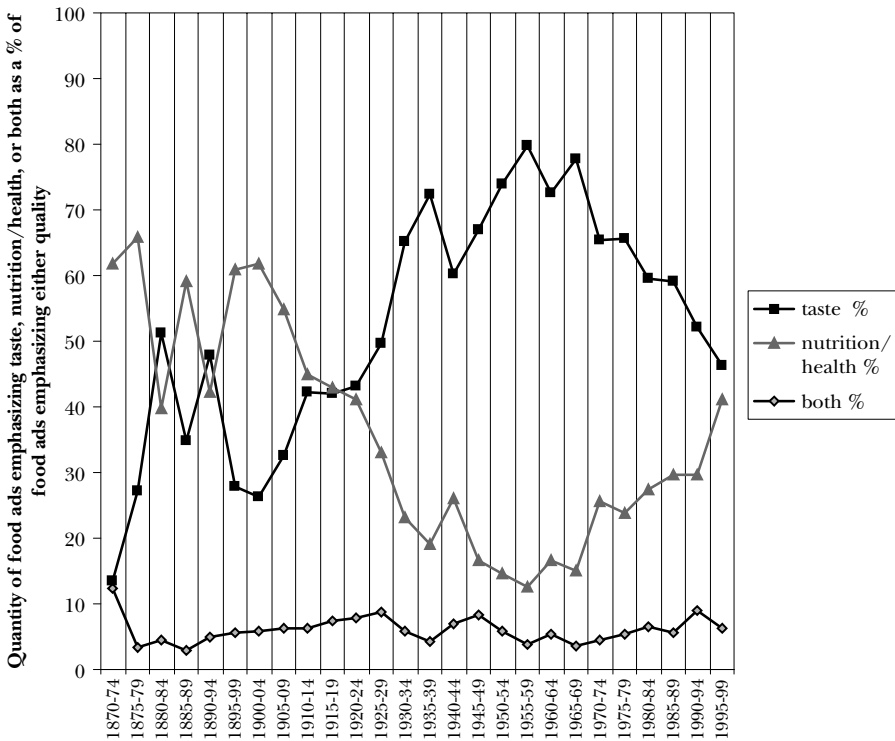
<sup>160</sup> *Id.*

<sup>161</sup> *Id.* (stating that the word drug "formerly" had this meaning). In addition, Webster's noted for the first time an emerging special meaning for "drug": "a narcotic substance or preparation." *Id.* Funk & Wagnalls included "narcotic" as a colloquial meaning for "drug" as early as 1897. FUNK & WAGNALLS, *supra* note 46, at 559.

<sup>162</sup> Federal Food, Drug, and Cosmetic Act, ch. 675, § 201(f), 52 Stat. 1040, 1040 (1938) (current version at 21 U.S.C. § 321(f) (2000)).

nate[ ] any doubt as to whether or not [it is] food.”<sup>163</sup> By contrast, a 1937 House bill omitted the terms “confectionery” and “condiment” from the definition of food, without explanation, and these words never appeared again.<sup>164</sup> Apparently, the cultural conception of “food” had evolved to the point that a product used primarily or exclusively for taste, rather than nutritive content, clearly fit within the “food” category. Evidence for this development lies in a dramatic shift in the ratio of instances in which food advertisers emphasized the taste qualities of food as compared with those instances in which they stressed food’s nutritive value and health benefits.<sup>165</sup>

FIGURE 1



<sup>163</sup> *Hearing on H.R. 6906, H.R. 8805, H.R. 8941 and S. 5 to Regulate Foods, Drugs, and Cosmetics Before H. Subcomm. of the Comm. on Interstate and Foreign Commerce, 74th Cong. 1 (1935) [hereinafter *Hearing to Regulate Foods, Drugs, and Cosmetics*] (statement of Walter G. Campbell, Chief of the FDA, Dep’t of Agric.), reprinted in 4 A LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND ITS AMENDMENTS 312, 370 (1979) [hereinafter *FDA HISTORY*].*

<sup>164</sup> H.R. 7913, 75th Cong. § 6 (1937).

<sup>165</sup> This graph was constructed from the results of a ProQuest search. ProQuest search of “Historical Newspapers,” “Display Ads” database (Sept. 13, 2007) (search terms: <(food or drink or beverage or meal or snack or breakfast or lunch or dinner) w/5 (tast\* or flavor\* or flavour\* or delicious)> and <(food or drink or beverage or meal or snack or breakfast or lunch or dinner) w/5 (nutr\* or nourish\* or health\*)>).

As the graph shows, during the decade in which Congress passed the 1906 Act, newspaper advertisers boasted about the nutritive and health qualities of food far more frequently than its taste. By the 1930s, however, advertisements associated food with flavor far more frequently than with its nutritive and health value. This shift may have been caused in part by the 1906 passage of the Pure Food and Drugs Act, which prohibited food misbranding, and the 1914 enactment of the Federal Trade Commission Act, which gave the Federal Trade Commission (FTC) the authority to prohibit false and deceptive advertising.<sup>166</sup> Food companies, denied the ability to make bogus health and disease claims, had to promote some feature of their products, and taste was an obvious alternative.<sup>167</sup> As advertisements increasingly encouraged Americans to consider taste an important characteristic of food, the cultural concept of food began to embrace condiments and confectionery more clearly.

In drafting the 1938 Act's definition of "drug," Congress confronted the limits of its power to establish legal categories that were inconsistent with extralegal cultural understandings. Bills introduced by Senator Royal Copeland between 1933 and 1935 extended the FDA's authority to medical devices by including "devices" within the definition of "drug."<sup>168</sup> Another senator caustically remarked: "[T]o maintain that a purely mechanical device is a drug and to be treated as a drug in law and in logic and in lexicography is a palpable absurdity. . . . [It] is the same thing as if the Congress of the United States should attempt to say by law that calling a sheep's tail a leg would make it a leg."<sup>169</sup> Apparently persuaded by this reasoning, Copeland soon afterward amended his bill to define "devices" separately from "drugs."<sup>170</sup>

Congress preserved, in slightly amended form, the provisions of the 1906 Act's drug definition that embraced articles recognized in the official compendia and articles "intended for use in the diagnosis,

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<sup>166</sup> See Hutt, *supra* note 135, at 9 ("From its inception, the FTC regarded false or misleading labeling and advertising of food products as unfair methods of competition."); see also *id.* at 27 ("Unwarranted health claims for staple foods appear to have largely disappeared in the first decade under the 1906 Act.")

<sup>167</sup> Advertisers also stressed other qualities of food, particularly convenience, which became one of the main bragging points in food advertising by the 1950s. HARVEY A. LEVENSTEIN, *PARADOX OF PLENTY: A SOCIAL HISTORY OF EATING IN MODERN AMERICA* 101-09 (1993).

<sup>168</sup> S. 5, 74th Cong. § 201(b)(2) (1st Sess. 1935), *reprinted in* 3 FDA HISTORY, *supra* note 163, at 2; S. 2800, 73d Cong. § 2(b)(2) (2nd Sess. 1934), *reprinted in* 1 FDA HISTORY, *supra* note 163, at 760; S. 1944, 73d Cong. § 2(b)(2) (1st Sess. 1933), *reprinted in* 1 FDA HISTORY, *supra* note 163, at 2.

<sup>169</sup> 74 CONG. REC. S4841 (Apr. 2, 1935) (statement of Sen. J. Bennett Clark), *reprinted in* 3 FDA HISTORY, *supra* note 163, at 797.

<sup>170</sup> S. 5, 74th Cong. (1st Sess. 1935) (as amended by S. Comm. on Commerce, May 13, 1935), *reprinted in* 4 FDA HISTORY, *supra* note 163, at 109-10.



cure, mitigation, treatment, or prevention of disease in man or other animals.”<sup>171</sup> The 1938 Act, however, also added an important third meaning to the definition of drug: “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”<sup>172</sup> The legislative history suggests that when inserting the structure-function language, Congress did not have in mind the dizzying variety of structure-function claims that now populate dietary supplement labels. The only type of structure-function drug specifically mentioned in the legislative history was “slenderizing” products.<sup>173</sup> Thus, it comes as no surprise that Congress exempted “food” from the new category of structure-function drugs; it did not want to convert every diet food into a drug. Moreover, as Peter Barton Hutt has pointed out, the “food” exclusion probably reflected the fact that “all food is intended to, and in fact does, affect the structure and function of the body.”<sup>174</sup>

Although the 1938 Act precluded the dual classification of a product as a food and a structure-function drug, Congress clearly intended to allow the FDA to classify articles as foods and “disease” drugs simultaneously.<sup>175</sup> Walter G. Campbell, the FDA Chief, testified in a 1934 hearing: “There are perhaps a hundred or more products

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<sup>171</sup> Federal Food, Drug, and Cosmetic Act, ch. 675, § 201(g)(2), 52 Stat. 1040, 1041 (1938) (current version at 21 U.S.C. § 321(g)(1)(B) (2000)).

<sup>172</sup> *Id.* § 201(g)(3), 52 Stat. at 1041 (current version at 21 U.S.C. § 321(g)(1)(C)). The structure-function concept found its way into Webster’s in 1961, when the THIRD NEW INTERNATIONAL DICTIONARY—the first major revision since 1934—quoted the 1938 Act, rather than the 1906 Act. WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 695 (3d ed. 1961).

<sup>173</sup> See *Hearings on S. 2800 Before the S. Comm. on Commerce*, 73d Cong. 516 (2d Sess. 1934) [hereinafter *Hearings on S. 2800*] (statement of Walter G. Campbell, Chief of the FDA, Dep’t of Agric.), reprinted in 2 FDA HISTORY, *supra* note 163, at 519; S. REP. NO. 361, at 3 (1935), reprinted in 3 FDA HISTORY, *supra* note 163, at 662; *Hearing to Regulate Foods, Drugs, and Cosmetics*, *supra* note 163, at 55 (statement of Walter G. Campbell, Chief of the FDA, Dep’t of Agric.), reprinted in 4 FDA HISTORY, *supra* note 163, at 370 (“The primary purpose of that particular definition, which, admittedly, is inclusive, is to reach the use of fat reducers, particularly since obesity may not be a disease.”). Medical devices were also defined with respect to structure-function effects, and the legislative history suggests that Congress envisioned that devices might be intended to affect structure and function in ways other than “slenderizing” the body. S. REP. NO. 361, at 3 (1935), reprinted in 3 FDA HISTORY, *supra* note 163, at 662. One hearing witness mentioned, for example, nose-straightening devices, scissors, and razors. See *Hearings on S. 2800*, *supra* at 318 (statement of Florence E. Wall), reprinted in 2 FDA HISTORY, *supra* note 163, at 321. The Chief of the FDA testified that the definition of device should embrace “a great many products that are advocated for changing the physical appearance of the person,” such as “heighteners.” *Hearings on S. 2800*, *supra*, at 516 (statement by Walter G. Campbell, Chief of the FDA, Dep’t of Agric.), reprinted in 2 FDA HISTORY, *supra* note 163, at 519.

<sup>174</sup> Hutt, *supra* note 135, at 24.

<sup>175</sup> S. REP. NO. 493, at 2 (1934) (calling specific authorization of dual classification “superfluous,” since “there has never been a court decision to the effect that these definitions are mutually exclusive”).

which have a dual [food and drug] use.”<sup>176</sup> How, then, did Congress intend for the agency to determine whether such a product was a “food,” a “drug,” or both? In one of the most-quoted passages from the legislative history of the 1938 Act, a Senate Report explained:

The use to which the product is to be put will determine the category into which it will fall. If it is to be used only as a food it will come within the definition of food and none other. If it contains nutritive ingredients but is sold for drug use only, as clearly shown by the labeling and advertising, it will come within the definition of drug, but not that of food. If it is sold to be used both as a food and for the prevention or treatment of disease it would satisfy both definitions and be subject to the substantive requirements for both. The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put.<sup>177</sup>

In a recent case regarding whether the FDA had regulatory authority over tobacco products, the parties starkly disagreed about the precise significance of this passage.<sup>178</sup> It is unclear what, if anything, the paragraph says about situations in which the manufacturer has made no representations regarding the use to which its product should be put. A straightforward reading, however, suggests at least that the manufacturer of a dual-use food-drug can, through representations it makes in labeling and advertising, control whether the product will be classified as a “food,” a “drug,” or both. This important principle has eliminated much of the uncertainty about the categorization of such products.

The 1938 Act revised the misbranding standard for therapeutic claims in a way that helped further differentiate food and drug labeling. The Pure Food and Drugs Act, as revised in 1912, had stated that a drug was misbranded if its label contained a “false and fraudulent” statement regarding “curative or therapeutic effect.”<sup>179</sup> The requirement of demonstrating fraud made this a difficult standard for the

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<sup>176</sup> *Hearings on S. 2800, supra* note 173, at 515 (statement of Walter G. Campbell, Chief of the FDA, Dep’t of Agric.), *reprinted in* 2 FDA HISTORY, *supra* note 163, at 518.

<sup>177</sup> S. REP. NO. 493, at 2–3.

<sup>178</sup> *Compare* Brief for Respondent R.J. Reynolds at \*12–14, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (No. 98-1152), 1999 WL 712566 (arguing that the passage means that a product cannot be “intended to” be put to a certain use unless the manufacturer suggests this use in representations made in connection with its sale), *with* Reply Brief for Petitioners at \*6–7 & n.3, *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (No. 98-1152), 1999 WL 33609281 (arguing that the phrase “can determine” in the passage means that the presence or absence of a manufacturer representation is not always dispositive and that the question the passage addresses—whether a product concededly subject to the Act constitutes a “food,” “drug,” or both—is a different question from whether a product, like a cigarette, is subject to the Act in the first place).

<sup>179</sup> Law of Aug. 23, 1912, ch. 352, § 8, 37 Stat. 416, 417 (1912).

FDA to satisfy.<sup>180</sup> Although the agency had some success in enforcing the Pure Food and Drugs Act's misbranding provisions after 1912,<sup>181</sup> disease claims did not disappear from food labels.<sup>182</sup> The 1938 Act relaxed the standard from "false and fraudulent" to "false or misleading in any particular," a change that greatly eased the FDA's burden in proving misbranding.<sup>183</sup> In part because of this revision, in the first fifteen to twenty years following the passage of the 1938 Act, conventional food items rarely made claims about their effects on specific diseases.<sup>184</sup>

The 1938 Act also introduced a requirement that the manufacturer of a "new drug" (defined as a drug not generally recognized as safe<sup>185</sup>) submit to the FDA a New Drug Application (NDA) setting forth the company's evidence of the drug's safety.<sup>186</sup> The introduction of premarket drug review, in conjunction with other trends, transformed the popular conception of the term "drug" dramatically. After 1938, in the words of Philip J. Hiltz, "the pharmaceutical industry went from a handful of chemical companies with no interest in research and no medical staffs to a huge machine that discovered,

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<sup>180</sup> See *Hearings on S. 1944 Before a S. Subcomm. on S. 1944*, 73d Cong. 41–44 (2d Sess. 1933) (statement of Walter G. Campbell, Chief of the FDA, Dep't of Agric.), *reprinted in 1 FDA HISTORY*, *supra* note 163, at 133–36 (describing the difficulties of bringing enforcement actions for false curative claims under the 1906 Act as amended).

<sup>181</sup> HUTT, MERRILL, & GROSSMAN, *supra* note 79, at 472 (listing cases); *see, e.g.*, *Seven Cases v. United States*, 239 U.S. 510, 518–19 (1916) (holding that Eckman's Alterative violated the 1906 Act because the product's label stated that it would prevent pneumonia and cure tuberculosis, and the manufacturer intended this statement to deceive purchasers).

<sup>182</sup> See LEVENSTEIN, *supra* note 167, at 13–14; LEVENSTEIN, *supra* note 53, at 152–54, 197–98 (providing examples of food manufacturers' disease claims).

<sup>183</sup> Federal Food, Drug, and Cosmetic Act, ch. 675, § 502(a), 52 Stat. 1040, 1050 (1938) (current version at 21 U.S.C. § 352(a) (2000)). The 1938 Act also expanded FDA's power over disease claims for food by introducing a broad definition of "labeling" that included any statements "accompanying" a product, not just those statements on the labels themselves, and by requiring that omissions of material facts, as well as explicit representations, be taken into account when determining misbranding. *Id.* § 201(k), (m)–(n), 52 Stat. at 1041 (current version at 21 U.S.C. § 321(k), (m)–(n)).

<sup>184</sup> See Hutt, *supra* note 135, at 27–28.

<sup>185</sup> Federal Food, Drug, and Cosmetic Act, § 201(p)(1), 52 Stat. at 1041–42 (current version at 21 U.S.C. § 321(p)(1)).

<sup>186</sup> *Id.* § 505(b), 52 Stat. at 1052 (current version at 21 U.S.C. § 352(b)). Unlike today, the manufacturer did not have to wait for FDA approval before selling the drug; the right to market automatically commenced sixty days after the manufacturer filed the NDA, unless the agency objected. *Id.* § 505(c), 52 Stat. at 1052 (current version at 21 U.S.C. § 355(c)). Also unlike today, the NDA did not have to establish the drug's efficacy. *See id.* § 505(d), 52 Stat. at 1052 (current version at 21 U.S.C. § 355(d)). The NDA requirement was added in 1937, at the very end of the amendment process, in response to the deaths of 107 people, many of whom were children, from an adulterated elixir of sulfanilamide. *See S. Res 194*, 75th Cong. (1937) (enacted), *reprinted in 5 FDA HISTORY*, *supra* note 163, at 871; *S. REP. NO. 124*, at 1–34 (1937), *reprinted in 5 FDA HISTORY*, *supra* note 163, at 883–921. The NDA obligation applied to few products that bridged the food–drug line, because such articles were, for the most part, "generally recognized as safe" and thus not "new drugs." *See supra* note 185 and accompanying text.

developed, and marketed drugs of real use in treating disease.”<sup>187</sup> This revolution stemmed in part from the pharmaceutical industry’s recognition that it needed scientists and laboratories to comply with the 1938 regulatory regime. These drastic changes were also impelled by pre-World War II successes in laboratory-based drug synthesis and a general faith in science inspired by the contributions of scientific researchers to the Allied war effort.<sup>188</sup> Before this transformation, drug companies were primarily distributors of natural vegetable and chemical substances that they merely put into usable dosage forms and combined into proprietary combinations; afterward, they were scientific enterprises that sold new chemical entities synthesized in the laboratory.<sup>189</sup> As Hilts observes: “More new and truly effective drugs were invented between 1935 and 1955 than in all of previous human history. By the early 1950s, 90 percent of the prescriptions filled by patients were for drugs that did not even exist in 1938.”<sup>190</sup>

In sum, after the enactment of the 1938 Act, the drug market was increasingly dominated by precisely characterized new chemical entities manufactured under carefully controlled conditions.<sup>191</sup> This transformation of the pharmaceutical industry inevitably affected the public’s notion of the prototypical “drug,” pulling the common understanding of the term further and further away from the nineteenth century’s paradigmatic “drug simple” derived from vegetable matter.<sup>192</sup> The blurry line between “food” and “drug” became more defined. The border between the categories became even more distinct in 1951, when the Durham-Humphrey Amendments to the FD&C Act gave the FDA another power over drugs that it did not have over food: the authority to mandate prescription status.<sup>193</sup>

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<sup>187</sup> PHILIP J. HILTS, *PROTECTING AMERICA’S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION* 95 (2003).

<sup>188</sup> *See id.* at 93–94, 104.

<sup>189</sup> *See id.* at 93 (“[The 1938 Act] came at a time when the drug industry was just beginning to realize that the nature of its business in the future was not to stamp out millions of identical bottles of chemicals, but rather to fashion drugs that could attack the underlying bases of disease. . . . The 1938 law made it clear that companies could not survive without scientists and laboratories.”).

<sup>190</sup> *Id.* at 105.

<sup>191</sup> *See supra* notes 187–90 and accompanying text.

<sup>192</sup> *See supra* notes 187–90 and accompanying text.

<sup>193</sup> Durham-Humphrey Amendment, ch. 578, § 503(b)(1), 65 Stat. 648, 648 (1951) (current version at 21 U.S.C. §§ 353–355 (2000)). *See generally* Charles Wesley Dunn, *The New Prescription Drug Law: Enacted by the Durham Bill (H. R. 3298) as a Part of the Federal Food, Drug, and Cosmetic Act*, 6 FOOD DRUG COSM. L.J. 951 (1951) (describing three parts of the Durham-Humphrey Amendment). Even before 1951, the FDA had effectively established mandatory prescription status through regulation. *See* Edward B. Williams, *Exemption from the Requirement of Adequate Directions for Use in the Labeling of Drugs*, 2 FOOD DRUG COSM. L.Q. 155, 159 (1947).

## B. The Story of Vitamin Pills Under the 1938 Regime

Beginning in 1911, scientists isolated and identified a series of substances they called “vitamins” and explored the association between vitamin deficiencies and disease.<sup>194</sup> By the 1920s, American food advertisers were liberally proclaiming that their vitamin- and mineral-rich products would promote health, growth, and longevity.<sup>195</sup> The middle class acquired a widespread vitamin consciousness that soon flowered into “vitamin-mania.”<sup>196</sup> Until scientists developed methods for commercially synthesizing vitamins in the 1930s, however, only manufacturers of conventional food (and products like yeast tablets and cod-liver oil) could exploit the vitamin craze.<sup>197</sup> Pharmaceutical companies began using irradiation to produce vitamin D supplements in the early 1930s.<sup>198</sup> In the mid-1930s, further advancements in commercial synthesis allowed manufacturers to mass produce other vitamins in liquid, tablet, and capsule form.<sup>199</sup> By 1938, vitamin supplements were the second most popular items on drugstore shelves, following only laxatives.<sup>200</sup>

A 1935 Senate bill added a provision to the proposed “Federal Food, Drugs, and Cosmetic Act” declaring any food to be misbranded “[i]f it purports to be or is represented for special dietary uses, such as by infants or invalids or for other nutritional requirements, and its label fails to bear, if so required by regulations . . . statements concerning its vitamin, mineral, and other dietary properties which fully inform the purchaser as to its nutritional value.”<sup>201</sup> The accompanying report explained that this provision dealt with articles “such as infant foods, invalid foods, slenderizing foods, and other dietary products intended for special nutritional requirements.”<sup>202</sup> The failure of the 1935 bill to specifically mention vitamin supplements is hardly surprising, for the commercial synthesis of vitamins was just starting to become practicable at that time.<sup>203</sup>

Vitamin capsules and tablets were extremely popular by the time the Act passed in 1938, but the “special dietary foods” provision as enacted in section 403(j) still did not refer directly to vitamin supplements.<sup>204</sup> Congress thus failed to resolve an important definitional

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194 See LEVENSTEIN, *supra* note 53, at 148.

195 See LEVENSTEIN, *supra* note 167, at 13; LEVENSTEIN, *supra* note 53, at 149–50, 152–53.

196 See LEVENSTEIN, *supra* note 167, at 12–14; LEVENSTEIN, *supra* note 53, at 147–60.

197 See LEVENSTEIN, *supra* note 167, at 12–16.

198 *Id.* at 19.

199 See *id.* at 19–20.

200 See *id.* at 20.

201 S. 5, 74th Cong. §302(j) (1935), reprinted in 3 FDA HISTORY, *supra* note 163, at 1, 8.

202 S. REP. NO. 361, at 12 (1935), reprinted in 3 FDA HISTORY, *supra* note 163, at 671.

203 See LEVENSTEIN, *supra* note 167, at 19; LEVENSTEIN, *supra* note 53, at 148–49.

204 Federal Food, Drug, and Cosmetic Act, ch. 675, § 403(j), 52 Stat. 1040, 1048 (1938) (current version at 21 U.S.C. § 343(j) (2000)).

question: Were vitamin pills “food” or “drugs”? The fact that vitamins are nutritive substances found naturally in foods tugged vitamin supplements strongly toward the “food” category. In the marketing battle that arose between conventional food processors and vitamin supplement manufacturers, however, the former fought fiercely to distinguish vitamin supplements from food (“Get your vitamins in food—it’s the thriftier way”<sup>205</sup>).

The fact that vitamin pills differed significantly from prototypical foods bolstered the food industry’s efforts to differentiate vitamin supplements from conventional food products. Vitamins failed two of the four attributes in the “cluster model” of food that I set forth earlier; they were swallowed and used for nutritive value, but they were not—in the days before children’s chewable vitamins—chewed or used for taste.<sup>206</sup> Moreover, vitamins did not fall within the triad of complex organic substances—proteins, carbohydrates, and fats—that had long been deemed to be the sole building blocks of food.<sup>207</sup> Webster’s 1934 definition of “food” referred to these three substances and then stated that vitamins (along with water and salts) were “not ordinarily classed as foods.”<sup>208</sup>

Finally, another likely reason why vitamin pills did not fit comfortably within the “food” category was the fact that they shared multiple attributes with prototypical drugs. Vitamin supplements were marketed in drug-like dosage forms and in drug-like packaging. They were widely discussed and advertised as preventing all manners of ailments. Moreover, in the 1930s, they were manufactured primarily by pharmaceutical companies and sold largely—in some states exclusively—through drugstores, frequently by prescription.<sup>209</sup> As scholars have stressed, the presence of contrasting categories may constitute a critical aspect of a system of categorization.<sup>210</sup> In this instance, the very existence of the contrasting cultural category “drug” may have limited the range of items embraced by the category “food.” Many

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<sup>205</sup> LEVENSTEIN, *supra* note 167, at 20.

<sup>206</sup> See *supra* text accompanying note 29, Parts II.A, III.A; *infra* Part IV. The earliest advertisement I could find for chewable vitamins was published in 1957. WASH. POST, Apr. 11, 1957, at D13 (containing an advertisement promoting a “candy flavored, chewable multiple vitamin”).

<sup>207</sup> See WEBSTER’S 1934, *supra* note 156, at 982.

<sup>208</sup> *Id.*

<sup>209</sup> See LEVENSTEIN, *supra* note 167, at 14; LEVENSTEIN, *supra* note 53, at 148–55.

<sup>210</sup> LAKOFF, *supra* note 14, at 50–52. For example, as Lakoff points out, within the “superordinate category of things-to-sit-on,” the range of objects covered by the basic-level category “chair” would almost certainly be different if the contrasting categories “stool,” “sofa,” and “bench” did not exist. *Id.* at 52.

people seem initially to have placed vitamin pills into the former conceptual box rather than the latter.<sup>211</sup>

The drugstore monopoly over vitamin retailing in some states emerged because drugstore lobbyists persuaded state legislatures to classify vitamin supplements as drugs, thereby restricting the sale of vitamin supplements to pharmacies.<sup>212</sup> Grocery stores and department stores hoping to profit from the vitamin boom were thus the first litigants to advance the argument that vitamin pills were food. For example, in 1939, the Kroger Grocery chain challenged an Indiana Board of Pharmacy rule limiting vitamin sales to drugstores.<sup>213</sup> The Superior Court ruled in favor of Kroger, holding that vitamins are “accessory food factors,”<sup>214</sup> and the Appellate Court upheld this decision.<sup>215</sup> In an impassioned dissent to a denial of rehearing, one judge pointed out that the vitamins in question “were made synthetically by pharmaceutical manufacturers, and never were part of any food or edible thing.”<sup>216</sup> Even if they were derived from food, he pointed out, “[t]he books abound in the instances wherein those substances, which we always refer to as drugs . . . are obtained from substances commonly used as food.”<sup>217</sup> This was a dissent, however.

In 1940, the FDA promulgated proposed regulations pursuant to section 403(j) that required, among other things, “minimum daily requirement” labeling on food purporting to have a “special dietary use . . . based in whole or in part on its vitamin [or mineral] prop-

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<sup>211</sup> See, e.g., *Standard Brands, Inc. v. Smidler*, 151 F.2d 34, 43 (2d Cir. 1945) (Frank, J., concurring) (reluctantly agreeing that the manufacturer of V-8 vitamin tablets infringed the trademark of V-8 vegetable juice, but noting, “I know that I, for one, would never think that defendant’s tablets, sold in drug-stores, are the product of the manufacturer of ‘V-8’ vegetable-juice, sold in food-stores and restaurants”).

<sup>212</sup> See *id.* at 20.

<sup>213</sup> *Dep’t of State v. Kroger Grocery & Baking Co.*, 40 N.E.2d 375, 376 (Ind. App. 1942).

<sup>214</sup> *Kroger Grocery & Baking Co. v. Dep’t of State*, Marion County Sup. Ct., IN, *quoted in Public Hearing on Food for Special Dietary Uses Transcript*, 57–58 (Oct. 7, 1940) [hereinafter *Hearing on Special Dietary Uses*] (on file with author).

<sup>215</sup> See *Kroger*, 40 N.E.2d at 375; see also *King v. Bd. of Medical Examiners*, 151 P.2d 282, 286 (Cal. Dist. App. 1944) (holding that a “drugless practitioner” who was not authorized to prescribe drugs did not violate his license by prescribing mineral and vitamin capsules); *Bd. of Pharmacy v. Quackenbush & Co.*, 39 A.2d 28 (N.J., Ct. Comm. Pleas Passaic County 1940) (dismissing the complaint against defendant department store operator because vitamins are considered “essentially a food product”); cf. *Cowdery v. Shafer*, 58 Pa. D. & C. 290, 299 (Pa., Ct. Comm. Pleas Dauphin County 1946) (holding that the license of a “drugless practitioner” was properly revoked because he dispensed herb and vegetable capsules for the purpose of treating, curing, or mitigating disease).

<sup>216</sup> *Dep’t of State v. Kroger Grocery & Baking Co.*, 41 N.E.2d 952, 952 (Ind. App. 1942) (Stevenson, J., dissenting).

<sup>217</sup> *Id.* at 953.

erty.”<sup>218</sup> Whether this rule applied to vitamin supplements as well as conventional foods was unclear, because the rule did not address whether supplements were “food” in the first place. All the other labeling regulations in the proposed rule applied to products in conventional food form, such as infant food, weight-control food, and hypoallergenic food.<sup>219</sup>

At the ensuing public hearings, the Kroger Grocery Company contended that the FDA should categorize vitamin supplements as food so as to promote their sale and consumption, particularly among lower-income groups.<sup>220</sup> If the FDA treated vitamin supplements as drugs, Kroger warned, state boards of pharmacy would, as in Indiana, pass restrictive regulations limiting the sale of vitamins to pharmacies, which had higher prices and were less plentiful than grocery stores.<sup>221</sup> Kroger then observed:

Milk and orange juice may be specifically prescribed in the treatment of a definite disease. Beef steak may be used to heal a black eye. In these cases foods function as medicines, but no one could seriously contend that they are generally drugs. . . . The occasional use of vitamins to cure disease does not alter the inherent dietary character of vitamin concentrates.<sup>222</sup>

In response, the National Association of Retail Druggists (NARD) did not take as extreme a position as Kroger seemed to anticipate. NARD conceded that not all vitamin products and preparations should be treated as drugs, but argued that if a vitamin’s labeling mentioned ailments and diseases, “the question . . . is automatically determined by the language of Section 201(g) of the Federal Act.”<sup>223</sup> A representative of the U.S. Vitamin Corporation contended that vitamin tablets, capsules, elixirs, and concentrates, “as against commonly accepted foods, fortified with vitamins,” might be food, drugs, or cos-

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<sup>218</sup> In the Matter of Prescription Label Statements Concerning Dietary Properties of Food Purporting to Be or Represented for Special Dietary Uses: Notice of Public Hearing, 5 Fed. Reg. 3565, 3565 (Sept. 5, 1940).

<sup>219</sup> See *id.* at 3565–66.

<sup>220</sup> *Hearing on Special Dietary Uses*, *supra* note 214, at 53–54 (statement of Kroger Grocery & Baking Co.). This argument had added weight at that time, just before the bombing of Pearl Harbor, because experts were concerned that widespread malnutrition would weaken the United States in its looming conflict with the fascist powers. See LEVENSTEIN, *supra* note 167, at 64–68 (discussing the perception of widespread vitamin deficiencies in the early 1940s).

<sup>221</sup> *Hearing on Special Dietary Uses*, *supra* note 214, at 54–56 (statement of Kroger Grocery & Baking Co.).

<sup>222</sup> *Id.* at 60; see also *id.* at 204 (statement of Madeline Ross, Consumer’s Union of U.S., Inc.) (stating that vitamin and mineral supplements “are part of the diet, and are dietary foods in the true sense of the words”).

<sup>223</sup> *Id.* at 115 (statement Mr. Jones, National Association of Retail Druggists).



metics, “depending on the composition of the product, the purpose for which it is used, and its labeling.”<sup>224</sup>

The 1941 final rule, mandating “recommended daily allowance” labeling of vitamin and mineral content, still did not explicitly cover supplements.<sup>225</sup> Nonetheless, it strongly implied that such products were special dietary foods by defining “special dietary uses” to include “[u]ses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral or other dietary property.”<sup>226</sup> Some residual confusion about the status of vitamin supplements existed as late as 1943, when a federal district court held that vitamin capsules were drugs, and not food, because they were listed and recognized in the U.S. Pharmacopoeia.<sup>227</sup> Nonetheless, from the mid-1940s on, both the FDA and the courts treated vitamin pills as food for special dietary uses, or, if their labeling bore disease claims, as both drugs and food for special dietary uses.<sup>228</sup> In 1973, the agency—over the objections of some comments—finally formally stated in a regulation that the term “food for special dietary use” embraced vitamins in supplement form.<sup>229</sup>

In 1986, former FDA Chief Counsel William Goodrich recalled that the agency’s decision in the early 1940s to treat vitamin supplements as food was based on nothing more than the “idea that they could deal with them better . . . as special dietary foods than they could as drug items, because the agency really didn’t have much experience with drugs at that time.”<sup>230</sup> The decision also, however, seemed to reflect an American cultural tendency to view food largely in terms

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<sup>224</sup> *Id.* at 116–17 (statement of H.E. Dubin, U.S. Vitamin Corp.).

<sup>225</sup> *See* Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 6 Fed. Reg. 5921, 5921 (Nov. 22, 1941) (codified at 21 C.F.R. pt. 2.10a); LEVENSTEIN, *supra* note 167, at 65–66 (describing the implementation of “recommended daily allowance” standards).

<sup>226</sup> Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 6 Fed. Reg. at 5921.

<sup>227</sup> *See* United States v. Harold Hain (S.D. Cal. 1943), *reprinted in* VINCENT A. KLEINFELD & CHARLES WESLEY DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT: JUDICIAL AND ADMINISTRATIVE RECORD 1938–1949, at 265, 266–67 (Food Law Institute Series No. 2, 1949).

<sup>228</sup> *See* V. E. Irons, Inc. v. United States, 244 F.2d 34, 39, 44 (1st Cir. 1957) (holding the supplement product was a “food for special dietary use” by virtue of its labeling indicating the presence of vitamins and minerals, and a drug, by virtue of its disease claims).

<sup>229</sup> *See* 21 C.F.R. § 125.1(a) (1973); Special Dietary Foods, 38 Fed. Reg. 2143, 2149 (Jan. 19, 1973) (codified at 21 C.F.R. pts. 1, 3, 125); Label Statements; Findings of Fact, Conclusions, and Final Order, 38 Fed. Reg. 20,708, 20,717 (Aug. 2, 1973) (codified at 21 C.F.R. pt. 125).

<sup>230</sup> Interview by Ronald T. Ottes & Fred L. Lofsvold with William W. Goodrich, Office of the General Counsel, FDA, in Rockville, Md. (Oct. 15, 1986), <http://www.fda.gov/oc/history/oralhistories/goodrich/default.htm> [hereinafter Goodrich Interview].

of its functional value.<sup>231</sup> The categorization of tasteless synthetic capsules as foodstuffs seems emblematic of the longstanding ethos among the country's elites and experts that people should "eat to live," not "live to eat."<sup>232</sup>

Interestingly, from a regulatory perspective, not much was at stake in the classification of vitamin pills as "food" or "drugs" in the 1940s. Even if categorized as the latter, vitamin supplements were generally recognized as safe and thus would not be "new drugs" subject to the NDA requirement.<sup>233</sup> Goodrich recalled that the main significance of the classification decision was the content of the label; food labels declared all their ingredients, whereas drug labels included only active ingredients.<sup>234</sup> The FDA later grew to regret the fact that vitamin pills were labeled according to food regulations, because it believed that vitamin manufacturers added ingredients with no nutritional value to their products, simply so that they could falsely suggest improved utility by listing these ingredients on the label.<sup>235</sup> This problem led Goodrich to conclude, "[W]e probably made a mistake in terms of classifying the vitamins as foods."<sup>236</sup>

Not until the late 1960s and 1970s, however, did it become obvious how significantly the categorization of vitamin and mineral supplements as food handcuffed the agency. In the early 1960s, the FDA launched a campaign against "health quackery," focusing largely on explicit disease claims for vitamin products.<sup>237</sup> Initially, the agency appeared to have the legal weapons it needed to conduct this war. Throughout the 1940s and 1950s, the FDA had successfully contended that vitamin supplements making disease claims were misbranded drugs,<sup>238</sup> and the agency continued to prevail with this approach dur-

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<sup>231</sup> See LEVENSTEIN, *supra* note 167, at 64–70 (discussing efforts by the government to shape the American diet to bolster the war effort in the 1940s); *supra* notes 69–77 and accompanying text.

<sup>232</sup> See LEVENSTEIN, *supra* note 53, at 79.

<sup>233</sup> See *supra* notes 185–86 and accompanying text.

<sup>234</sup> Goodrich Interview, *supra* note 230.

<sup>235</sup> See Hutt, *supra* note 135, at 57–69. The Vitamin-Mineral Amendments of 1976 prohibit the FDA from limiting the composition of vitamin-mineral supplements or declaring such a product misbranded because its label bears a complete ingredient listing. Vitamin-Mineral Amendments, Pub. L. No. 94-278, § 411(a)(1)(c), (b)(1), 90 Stat. 410, 410 (1976) (current version at 21 U.S.C. § 350(a)(1)(C), (b)(1) (2000)).

<sup>236</sup> Goodrich Interview, *supra* note 230.

<sup>237</sup> See LEVENSTEIN, *supra* note 167, at 167–68; Hutt, *supra* note 135, at 54–55.

<sup>238</sup> See Hutt, *supra* note 135, at 52–54. For two prominent examples of seizures of vitamin and mineral products as misbranded drugs, see *Kordel v. United States*, 335 U.S. 345 (1948); *United States v. Mytinger & Casselberry, Inc.* (S.D. Cal. 1951), *reprinted in* VINCENT A. KLEINFELD & CHARLES WESLEY DUNN, *FEDERAL FOOD, DRUG, AND COSMETIC ACT: JUDICIAL AND ADMINISTRATIVE RECORD 1951–1952*, at 204–13 (Food Law Institute Series No. 4, 1953).

ing the 1960s.<sup>239</sup> In 1973, after a protracted eleven-year process, the FDA further attacked the problem of “quack” vitamin and mineral claims by amending the 1941 special dietary foods regulation. The revised regulation stated explicitly that, in most instances, a product was misbranded if its labeling “represent[ed], suggest[ed], or imp[li]e[d]” that “the food, because of the presence or absence of certain vitamins and/or minerals, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.”<sup>240</sup> In addition, in the preamble to the revised regulation, the FDA asserted that “explicit claims related to prevention or treatment of specific disease conditions render a [vitamin-mineral] product a drug.”<sup>241</sup>

None of these initiatives addressed another problem, however. During the 1960s, a phenomenon that the FDA dubbed “nutritional mythology”<sup>242</sup> so permeated American culture<sup>243</sup> that labeling claims became almost irrelevant. Celebrity health food advocate Adelle Davis, in her bestselling books and television talk-show appearances, promoted the use of vitamin and mineral supplements as a weapon against disease.<sup>244</sup> Nobel Prize winner Linus Pauling endorsed the consumption of large doses of vitamin C as a treatment for the common cold and helped trigger a megavitamin craze, in which people attempted to cure a wide variety of ailments by gulping down massive doses of vitamins.<sup>245</sup> In this environment, supplement manufacturers did not need to make explicit disease claims themselves.

In the early 1970s, the FDA concocted a plan to apply the drug regulatory regime to at least some vitamin and mineral supplements that did not make disease claims. Regulating such products as drugs, instead of food, would allow the agency to impose more elaborate labeling requirements on them (including “adequate directions for

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<sup>239</sup> See Hutt, *supra* note 135, at 55 n.333; see also *United States v. Vitasafe Formula M*, 226 F. Supp. 266, 278 (D.N.J. 1964) (holding that a vitamin and mineral capsule was both a food and a drug; a “food” “because its labeling recommends its use as and represents it to be of value as a dietary and nutritional supplement” and a “drug” “because its labeling recommends its use as and represents it to be of value as a curative or preventive of disease conditions”).

<sup>240</sup> Label Statements; Findings of Fact, Conclusions, and Final Order, 38 Fed. Reg. 20,708, 20,718 (Aug. 2, 1973) (to be codified at 21 C.F.R. pt. 125).

<sup>241</sup> *Id.* at 20,710. Moreover, the FDA prohibited the combination of vitamins or minerals with “[i]ngredients or products . . . which have not been shown to be essential to human nutrition.” *Id.* at 20,718.

<sup>242</sup> K. L. Milstead, Deputy Dir., Bureau of Enforcement, FDA, Address Before the Yonkers Academy of Medicine: Recent Developments in the Food and Drug Administration’s Program Against Nutritional Nonsense 4 (Oct. 9, 1962) (transcript available from the National Library of Medicine) (drawing attention to the “problem [of] a vast and growing ‘folklore’ or ‘mythology’ of nutrition”) (quoting George Larrick, FDA Comm’r, Address Before Congress on Medical Quackery (Oct. 1961)).

<sup>243</sup> *Id.* at 4–6 (discussing tactics and giving examples of “nutritional quacks”).

<sup>244</sup> LEVENSTEIN, *supra* note 167, at 164–65.

<sup>245</sup> *Id.* at 166.

use”);<sup>246</sup> limit them to prescription sale; or even to require the manufacturers, under the 1962 FD&C Act drug amendments,<sup>247</sup> to file premarket NDAs demonstrating both safety and effectiveness.<sup>248</sup> In 1973, the FDA issued a rule declaring that “[a]ny product containing more than the upper limit [150 percent<sup>249</sup>] of the U.S. RDA per serving . . . of a vitamin or mineral . . . is a drug.”<sup>250</sup> The agency explained that because there was “no known food or nutrition use of nutrients at such high levels,” such products were “in fact articles intended for use in the cure, mitigation, treatment, or prevention of disease in man” and thus fell within the drug definition.<sup>251</sup> Moreover, on the same day, the FDA issued twin rules stating that because of toxicity, oral preparations containing more than 10,000 International Units (IU) of vitamin A or more than 400 IU of vitamin D “are drugs subject to section 503(b)(1) of the [FD&C Act] and shall be restricted to prescription sale.”<sup>252</sup>

The United States Court of Appeals for the Second Circuit rejected the FDA’s approach. In *National Nutritional Foods Ass’n v. FDA*,<sup>253</sup> the court overturned the rule categorizing vitamin-mineral preparations exceeding 150 percent of the RDA as drugs.<sup>254</sup> It observed that a significant number of people, including women taking oral contraceptives, have “indisputable nutritional needs for potencies exceeding the upper limits.”<sup>255</sup> Consequently, the court maintained, “it cannot be said even as an objective matter that a given bottle of pills, each containing more than the upper limit of one or more nutrients, is not being used for nutritional purposes.”<sup>256</sup> While acknowledging that “a factfinder should be free to pierce all of a manufacturer’s subjective claims of intent . . . to find actual therapeutic intent on the basis of objective evidence in a proper case, such objective evidence would need to consist of something more than demonstrated uselessness as a food for most people.”<sup>257</sup>

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<sup>246</sup> Federal Food, Drug, and Cosmetic Act § 502(f), 21 U.S.C. § 352(f) (2000).

<sup>247</sup> See *infra* notes 277–79 and accompanying text.

<sup>248</sup> See *Nat’l Nutritional Foods Ass’n v. FDA*, 504 F.2d 761, 788 (2d Cir. 1974) (listing the added powers FDA would have over vitamin supplements if they were categorized as drugs).

<sup>249</sup> See *id.* at 790.

<sup>250</sup> Label Statements; Findings of Fact, Conclusions, and Final Order, 38 Fed. Reg. 20,708, 20,717–18 (Aug. 2, 1973) (codified at 21 C.F.R. pt. 125).

<sup>251</sup> *Id.* at 20,710.

<sup>252</sup> *Id.* at 20,723, 20,725.

<sup>253</sup> 504 F.2d 761.

<sup>254</sup> *Id.* at 789.

<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

<sup>257</sup> *Id.*

Three years later, in *National Nutritional Foods Ass'n v. Mathews*,<sup>258</sup> the same court struck down the FDA regulation imposing prescription drug status on high dose vitamin A and D supplements.<sup>259</sup> The Second Circuit acknowledged that the agency, in determining the “intended use” of a product, could look not only at labeling, promotional material, and advertising, but also to “any other relevant source.”<sup>260</sup> In rejecting the rule, however, the Second Circuit made clear that the agency would have to clear a very high evidentiary bar to support a determination that a vitamin product marketed without disease claims was a drug. In a much-quoted passage, *Mathews* indicated that the FDA could categorize high-dose vitamin A and D preparations as drugs only if it provided evidence that they had no recognized nutritional use and were used “almost exclusively for therapeutic purposes.”<sup>261</sup>

In these two decisions, the Second Circuit thus made it almost impossible for the FDA, in the absence of disease claims, to categorize a vitamin-mineral supplement as a drug “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.”<sup>262</sup> Late in the process of defending its regulations, the FDA also advanced an alternative theory, based on the official compendia provision of the drug definition.<sup>263</sup> The agency contended that vitamins and minerals were drugs under this provision merely by virtue of being listed in the *U.S. Pharmacopoeia* and the *National Formulary*.<sup>264</sup> This theory had worked for the FDA on several previous occasions,<sup>265</sup> but in both of the Second Circuit cases, the court rebuffed this argument as an unacceptable post-hoc rationalization for the agency’s actions.<sup>266</sup> The court further stated that the FDA’s vitamin-mineral regulations were presumptively arbitrary if justified solely by this component of the

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<sup>258</sup> 557 F.2d 325 (2d Cir. 1977).

<sup>259</sup> *Id.* at 337–38.

<sup>260</sup> *Id.* at 334 (quoting *United States v. An Article . . . Consisting of 216 Cartoned Bottles . . . “Sudden Change,”* 409 F.2d 739 (2d Cir. 1969)).

<sup>261</sup> *Id.* at 334 (quoting *Nat’l Nutritional Foods Ass’n v. Weinberger*, 512 F.2d 688, 703 (2d Cir. 1975)).

<sup>262</sup> Federal Food, Drug, and Cosmetic Act § 201(g)(1)(B), 21 U.S.C. § 321(g)(1)(B) (2000).

<sup>263</sup> *See id.* § 201(g)(1)(A), 21 U.S.C. § 321(g)(1)(A).

<sup>264</sup> *See Nat’l Nutritional Foods Ass’n v. FDA*, 504 F.2d at 788–89 (addressing the FDA’s contention that “all the vitamins and presumably all the minerals with which we are here concerned are recognized in the official United States Pharmacopoeia or the official National Formulary”).

<sup>265</sup> *See Harold Hain, supra* note 227, at 267; *see also United States v. 39 Cases of . . . Korleen Tablets*, 192 F. Supp. 51, 51–52 (E.D. Mich. 1961); *United States v. Beuthanasia-D Regular*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,265, at 9-24-81 (D. Neb. 1979) (holding that an animal euthanasia substance is a drug and reasoning that “the [*USP*’s] recognition of the two active ingredients in the seized articles as drugs [is] decisive”).

<sup>266</sup> *See Mathews*, 557 F.2d at 337; *Nat’l Nutritional Foods Ass’n v. FDA*, 504 F.2d 761, 788–89 (2d Cir. 1974).

drug definition, because the agency had articulated no intelligible principle for treating some *USP*- and *NF*-listed products as drugs, but not others.<sup>267</sup>

The Second Circuit thus eliminated almost any uncertainty about the classification of vitamin pills; if the manufacturer did not represent them as curing, treating, or preventing disease, they were “food” and not “drugs.” Moreover, before *Mathews*, Congress had also acted to limit the FDA’s power over vitamin-mineral products. The Vitamin-Mineral Amendments of 1976<sup>268</sup> provided, among other things, that the agency “may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which [the FDA] determines is nutritionally rational or useful.”<sup>269</sup> Hence, by the end of the 1970s, no vitamin supplement without disease claims could be legally categorized as a “drug.”<sup>270</sup>

Yet, from a cultural perspective, have vitamin pills ever simply been “food”? The law has always seemed to acknowledge their ambiguous status by giving them a special classification within the broader food category—first “foods for special dietary uses,” now “dietary supplements.”<sup>271</sup> Meanwhile, the subcategory “foods for special dietary uses” continues to offer a legal harbor for other types of products that exist in the netherworld between food and drugs, including products with “[u]ses for supplying particular dietary needs which exist by rea-

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<sup>267</sup> See *Mathews*, 557 F.2d at 336–38; *Nat’l Nutritional Foods Ass’n*, 504 F.2d at 788–89; cf. *United States v. An Article of Drug . . . Ova II*, 414 F. Supp. 660, 665 (D.N.J. 1975), *aff’d without op.*, 535 F.2d 1248 (3d Cir. 1976) (explaining that the official compendia provision of the drug definition “cannot be taken literally,” because a literal interpretation would “run[ ] afoul of the principle that a legislative body may not lawfully delegate its functions to a private citizen or organization”).

<sup>268</sup> Vitamin and Mineral Amendment, Pub. L. No. 94–278, 90 Stat. 410 (1976) (current version in scattered sections of 21 U.S.C. (2000)).

<sup>269</sup> *Id.* § 411(a)(1)(B), 90 Stat. at 410 (current version at 21 U.S.C. § 350(a)(1)(B)). The amendment also prohibited the agency, under its food misbranding and food standards authority, from establishing limits on the potency of vitamins and minerals, and from limiting the permissible combinations of vitamins, minerals, and other food ingredients in such products. *Id.* § 411(a)(1)(A), (C), 90 Stat. at 410 (current version at 21 U.S.C. § 350(a)(1)(A), (C)). In 1979, the FDA revoked its various vitamin-mineral regulations. Food for Special Dietary Use: Vitamin and Mineral Products; Revocation of Regulations, 44 Fed. Reg. 16,005 (Mar. 16, 1979) (codified at 21 C.F.R. pts. 101, 105, 201).

<sup>270</sup> Although the FDA, as part of its Over-the-Counter Drug Review, proposed to regulate vitamin and mineral products above RDA-potency with certain claims as over-the-counter drugs, the FDA withdrew this effort under political pressure in 1981. Vitamin and Mineral Drug Products for Over-the-Counter Human Use; Withdrawal of Proposed Monograph, 46 Fed. Reg. 57,914, 57,914–15 (Nov. 27, 1981) (codified at 21 C.F.R. pt 345); see Hutt, *supra* note 135, at 64. Some vitamin products are still marketed as prescription drugs. See, e.g., *CMS Policy Reversal Gives Part D Plans the OK to Cover Rx Niacin*, FDA WEEK, Apr. 21, 2006, at 12, available at <http://www.INSIDEHEALTHPOLICY.COM> (allowing insurance coverage of prescription niacin).

<sup>271</sup> See *infra* Part V.B.

son of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases.”<sup>272</sup> Moreover, the 1983 Orphan Drug Act, reflecting a decade of FDA practice, established a category called “medical foods,” which are foods “formulated to be consumed or administered enterally under the supervision of a physician and which [are] intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements . . . are established by medical evaluation.”<sup>273</sup> In all these ways, federal food and drug law has implicitly acknowledged the absence of a firm line between “food” and “drug.”

#### IV

##### THE 1962 DRUG AMENDMENTS: THE IMPACT OF PREMARKET EFFECTIVENESS REVIEW

Under the 1938 premarket review process for drugs, an NDA filer did not have to wait for positive approval from the FDA; the applicant could commence marketing sixty days after filing if the agency did not object prior to that date.<sup>274</sup> Congress imposed a true premarket approval system on food additives before it imposed one on drugs. The 1958 Food Additives Amendment, still in effect today, decreed that the use of any “food additive”—defined to exclude substances generally recognized as safe—renders a food adulterated unless the use complies with an FDA food additive regulation.<sup>275</sup> The Amendment also established a procedure for petitioning the agency to issue such a regulation. The legislative history explained that the agency should approve a food additive petition only if the petitioner demonstrates, through the presentation of scientific evidence, “a reasonable certainty that no harm will result from the proposed use of an additive.”<sup>276</sup>

Four years later, the procedural burdens imposed on new drugs leapfrogged over those applicable to food additives. The 1962 Kefauver Drug Amendments significantly enhanced the FDA’s power over drugs, and it imposed new requirements on the drug industry that dramatically increased the cost of drug development. The

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<sup>272</sup> 21 C.F.R. § 105.3(a)(1)(i) (2007). The only special dietary food label regulations currently in effect concern hypoallergenic foods, infant foods, and weight-reduction foods. *Id.* § 105.3(a)(1)(i)(B).

<sup>273</sup> Federal Food, Drug, and Cosmetic Act § 529ee(b)(3), 21 U.S.C. § 360ee(b)(3) (2000); *see also* Hutt, *supra* note 135, at 70–71 (describing the agency’s special regulation of medical foods in the early 1970s); 21 C.F.R. § 101.9(j)(8) (defining medical foods).

<sup>274</sup> Federal Food, Drug, and Cosmetic Act, ch. 675, § 505(c), 52 Stat. 1040, 1052 (1938) (current version at 21 U.S.C. § 355(b)–(c) (2000)).

<sup>275</sup> Food Additives Amendment, Pub. L. No. 85-929, §§ 2, 4, 72 Stat. 1784, 1784, 1785–88 (1958) (current version at 21 U.S.C. §§ 321(s), 348 (2000 & Supp. V 2005)).

<sup>276</sup> S. REP. NO. 85-2422, at 6 (1958).

Amendments introduced the present system of premarket review, under which it is illegal to market a new drug prior to receiving positive FDA approval of an NDA.<sup>277</sup> In addition, the 1962 law redefined “new drug” to include any product not generally recognized as safe *or effective* and thus launched the requirement that new drug manufacturers demonstrate effectiveness, as well as safety, prior to marketing.<sup>278</sup> The Amendments established a “substantial evidence” standard for effectiveness, which could ordinarily be satisfied only by “adequate and well-controlled investigations, including clinical investigations, by [qualified] experts.”<sup>279</sup>

The Kefauver Amendments made it effectively impossible for any conventional food—or, for that matter, any natural product—to make a disease claim legally. Prior to 1962, the FDA could only regulate such claims reactively; that is, the agency had to allege that a product in commerce was misbranded and then carry the burden in court of establishing, by a preponderance of the evidence, that the claim in question was not scientifically supportable.<sup>280</sup> Under the 1962 drug amendments, almost any food making a disease claim was not only misbranded, but was also an unapproved, and thus illegally marketed, new drug.<sup>281</sup> To avoid this status, a food manufacturer making a disease claim would have to obtain prior FDA approval of an NDA setting forth “substantial evidence” of effectiveness. As a practical matter, virtually no food producer would start down this route, because most foods lacked patent protection. Without such protection, a manufacturer would never recover the significant costs of clinical testing and NDA preparation even if the application were ultimately approved. Moreover, the often prolonged time it took the FDA to approve an NDA was simply incompatible with food marketing.<sup>282</sup>

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<sup>277</sup> See Kefauver Amendments, Pub. L. No. 87-781, § 102(c)–(e), 76 Stat. 780, 781 (1962) (current version at 21 U.S.C. § 355(a)).

<sup>278</sup> *Id.* § 102(a)(1), 76 Stat. at 781 (current version at 21 U.S.C. § 321(p)(1)); see CENTER FOR DRUG EVALUATION AND RESEARCH, FDA, BENEFIT VS. RISK: HOW CDER APPROVES NEW DRUGS 5, available at <http://www.policyalmanac.org/health/archive/How%20CDER%20Approves%20New%20Drugs.pdf>.

<sup>279</sup> § 102(c), 76 Stat. at 781 (current version at 21 U.S.C. § 355(d)(7)).

<sup>280</sup> See Federal Food, Drug, and Cosmetic Act §§ 302, 304, 502(a), 21 U.S.C. §§ 332, 334, 352(a) (2000).

<sup>281</sup> A food making such a claim would avoid the definition of “new drug,” and thus the NDA requirement, only if it fell within a grandfather clause or if the food was “generally recognized . . . as safe and effective” for the labeled purpose. See *id.* § 102(a), 76 Stat. at 781 (current version at 21 U.S.C. § 321(p)(1)).

<sup>282</sup> E-mail from Peter Barton Hutt, Senior Counsel, Covington & Burling LLP, to author (Sept. 11, 2007) (on file with author); E-mail from Eugene I. Lambert, Senior Counsel, Covington & Burling LLP, to author (Sept. 10, 2007) (on file with author).



As a legal matter, dual food-drug classification survived the Kefauver Amendments<sup>283</sup> and, indeed, continues today.<sup>284</sup> Since 1962, however, dual food-drug products have existed almost exclusively in the world of legal concepts, not in the marketplace. To say that an article is both a food and drug under the current regulatory regime usually means that it is both a food and an unapproved new drug—that is, an *illegal* drug.

Between 1962 and the mid-1980s, the FDA used its new powers to attack foods that made explicit or implied disease claims.<sup>285</sup> Throughout this period, the agency steadfastly clung to the position that any conventional food making a claim with respect to a particular disease was a new drug, unless it was a special dietary food complying with section 403(j) regulations.<sup>286</sup> The FDA also fought against disease claims made by distributors of products such as herbs, botanicals, and food-derived substances.<sup>287</sup> As was true for conventional foods, an agency declaration that an herbal supplement or similar product was a new drug effectively constituted a market ban—without patent protection, nobody had adequate incentives to undertake the costly and uncertain new drug approval process.<sup>288</sup>

Distributors of some nonconventional food substances made structure-function claims, rather than disease claims, attempting to avoid drug classification by asserting eligibility for the parenthetical “other than food” exception in the structure-function drug definition.<sup>289</sup> This strategy provoked a legal battle over exactly what constituted a “food.” The main contest concerned the regulatory status of “starch blockers,” which were tablets and capsules containing a protein extracted from raw kidney beans. Manufacturers of these products claimed they controlled weight by inhibiting the human body’s digestion of starch.<sup>290</sup> In 1982, after the FDA sought to remove starch blockers from the market by classifying them as unapproved new drugs, the manufacturers sought a declaratory judgment rejecting the

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<sup>283</sup> See, e.g., *Rutherford v. United States*, 542 F.2d 1137, 1140 (10th Cir. 1976) (“[E]ven if a substance is also a food it may be subjected to [regulation as a drug] if it is used in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.”); *Hanson v. United States*, 417 F. Supp. 30, 35 (D. Minn. 1976) (“[P]laintiff’s argument that laetrile is a . . . food does not preclude its being a drug . . .”).

<sup>284</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 79, at 33–34.

<sup>285</sup> See generally Hutt, *supra* note 135, at 26–73 (discussing the FDA’s implementation of the 1938 Act with respect to health claims).

<sup>286</sup> *Id.* at 42–48, 65–66.

<sup>287</sup> See Milstead, *supra* note 242, at 1–14.

<sup>288</sup> See Federal Food, Drug, and Cosmetic Act § 201(p)(1), 21 U.S.C. §§ 321(p)(1), 355 (2000) (requiring the manufacturer of a “new drug” to demonstrate both safety and effectiveness prior to marketing).

<sup>289</sup> *Id.* § 201(g)(1)(C), 21 U.S.C. § 321(g)(1)(C).

<sup>290</sup> *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 335–36 (7th Cir. 1983).

agency's conclusion.<sup>291</sup> The manufacturers contended that starch blockers were "food," and thus within the parenthetical exclusion from the drug definition,<sup>292</sup> because they were derived from beans, and also because they were composed of protein, a substance often regarded as a food.<sup>293</sup>

In *Nutrilab, Inc. v. Schweiker*, the Seventh Circuit ruled in favor of the FDA.<sup>294</sup> The court opined:

Plaintiffs' argument that starch blockers are food because they are derived from food—kidney beans—is not convincing; if Congress intended food to mean articles derived from food it would have so specified. Indeed some articles that are derived from food are indisputably not food, such as caffeine and penicillin. In addition, all articles that are classed biochemically as proteins cannot be food either, because for example insulin, botulism toxin, human hair[,] and influenza virus are proteins that are clearly not food.<sup>295</sup>

To determine the meaning of "food" in the parenthetical exception to the structure-function drug definition, the Court of Appeals turned to the FD&C Act's definition of "food" in section 201(f).<sup>296</sup> The court held that the phrase "articles used for food or drink" in section 201(f) referred solely to "common-sense" foods.<sup>297</sup> The court thus essentially incorporated the extra-legal, cultural understanding of "food" directly into the law. It then set forth an extraordinarily influential elaboration, quoted frequently by the FDA ever since, of what "common sense" foods were: "articles used by people in the ordinary way most people use food—primarily for taste, aroma, or nutritive value."<sup>298</sup>

The court's description of the food category raises several interesting points. First, as the FDA itself has sometimes neglected to mention, the court referred to articles used *primarily* for taste, aroma, or

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<sup>291</sup> *Nutrilab, Inc. v. Schweiker*, 547 F. Supp. 880, 881 (N.D. Ill. 1982), *aff'd*, 713 F.2d 335 (7th Cir. 1983).

<sup>292</sup> See § 201(g)(1)(C), 21 U.S.C. § 321(g)(1)(C).

<sup>293</sup> *Nutrilab*, 547 F. Supp. at 882.

<sup>294</sup> *Nutrilab*, 713 F.2d at 338–39.

<sup>295</sup> *Id.* at 337.

<sup>296</sup> *Id.* at 338 (citation omitted) (analyzing the scope of the "parenthetical 'other than food' exclusion from the definition of drugs" in Federal Food, Drug, and Cosmetic Act § 201(g)(1)(C), 21 U.S.C. § 321(g)(1)(C) (2000)).

<sup>297</sup> *Id.* at 339. Because starch blockers were not "chewing gum," § 201(f)(2), 21 U.S.C. § 321(f)(2), or "articles used for components of" food, § 201(f)(3), 21 U.S.C. § 321(f)(3), the court deemed it unnecessary to decide whether the word "food" in the parenthetical exception from the drug definition referred to all of section 201(f) of the FD&C Act, or solely to section 201(f)(1), the "common-sense food" provision. See *id.*

<sup>298</sup> *Id.* at 338. The agency has referred to the "taste, aroma, or nutritive value" formulation at least 29 times in the Federal Register. LEXIS search in "FR-Federal Register" database (Mar. 10, 2008) (using the following terms: <AGENCY ("food and drug") and (taste pre/2 aroma pre/2 "nutritive value")>).

nutritive value.<sup>299</sup> The court explained that this qualifier was necessary because “some products such as coffee or prune juice are undoubtedly food but may be consumed on occasion for reasons other than taste, aroma, or nutritive value.”<sup>300</sup> Even this may not be a sufficient qualification, however; according to my informal polls, only a minority of law students who drink coffee do so primarily for its taste or aroma.

Second, the court’s inclusion of “taste” as a primary reason for consuming food was clearly uncontroversial by 1983. In light of developments such as the diet soda craze of the 1960s, the rising popularity of highly seasoned ethnic foods in the 1970s, and a generally “heightened appreciation for the pleasures of the table” throughout the period,<sup>301</sup> there was simply no denying that Americans often consumed foods mostly for their taste.<sup>302</sup> As Figure 1 shows, food advertisers focused increasingly on taste through the 1950s, and although assertions about nutrition and health have been making a comeback since then, flavor remains a chief emphasis in food advertising.<sup>303</sup> The Seventh Circuit’s reference in *Nutrilab* to articles used “primarily for . . . aroma” is both odd and superfluous; it seems to include air fresheners, while not embracing any true “common sense” foods not also covered by “taste,” “nutritive value,” or both.<sup>304</sup> The reference to “nutritive value,” although sensible, is ambiguous; as discussed below, the FDA still does not have a clear idea of what exactly this phrase means.<sup>305</sup>

A final notable aspect of the *Nutrilab* “common sense” food definition is that the definition does not exclude products consumed in a drug dosage form.<sup>306</sup> Indeed, the fact that starch blockers were sold as tablets and capsules did not enter into the court’s reasoning at all.<sup>307</sup> By 1983, the year the Seventh Circuit decided *Nutrilab*, the FDA had been regulating vitamin and mineral pills as food for more than forty years.<sup>308</sup> The following Part will describe how in 1994, the Diet-

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<sup>299</sup> The FDA has cabined “taste, aroma, or nutritive value” with the word “primarily” only 15 of the 29 times it has invoked the phrase in the Federal Register. See LEXIS search in “FR-Federal Register” database (Mar. 10, 2008) (search terms: <AGENCY (“food and drug”) and (taste pre/2 aroma pre/2 “nutritive value”)>).

<sup>300</sup> *Nutrilab*, 713 F.2d at 338.

<sup>301</sup> LEVENSTEIN, *supra* note 167, at 218.

<sup>302</sup> See *id.* at 213–26.

<sup>303</sup> See *supra* note 165 and accompanying figure.

<sup>304</sup> See *Nutrilab*, 713 F.2d at 338.

<sup>305</sup> See *infra* Part V.C.

<sup>306</sup> See *Nutrilab*, 713 F.2d at 338.

<sup>307</sup> For an example of an opinion that takes this into account, see *Millet, Pit & Seed Co. v. United States*, 436 F. Supp. 84, 90–91 (E.D. Tenn. 1977) (finding that apricot kernels, widely used as a cancer remedy, were food, in part because they were sold in their natural state and not in “pill, capsule, or liquid form”).

<sup>308</sup> See *supra* Part III.B.

ary Supplement Health and Education Act amended the FD&C Act to sweep into the “food” category an enormous universe of additional substances sold in drug dosage forms.<sup>309</sup> Today, starch blockers are, as a legal matter, “food.”

## V

## THE AMENDMENTS OF THE EARLY 1990S: FOOD IMPERIALISM

Through the 1970s and 1980s, growing societal and political pressure was aimed at lifting the rigorous requirement of premarket drug review from foods and “natural” products making health-related claims. In the early 1990s, Congress responded to these demands with two important amendments to the FD&C Act: the Nutrition Labeling and Education Act of 1990 (NLEA)<sup>310</sup> and the Dietary Supplement Health and Education Act of 1994 (DSHEA).<sup>311</sup> The former permitted conventional foods, under certain conditions, to make explicit disease prevention claims without subjecting themselves to the drug regime.<sup>312</sup> The latter recharacterized various types of products that did not satisfy the *Nutrilab* “taste, aroma, or nutritive value” test as food and permitted them to make structure-function claims, and sometimes disease-prevention claims, without falling into the “drug” category.<sup>313</sup> These changes to the FD&C Act have significantly reshaped the legal categories of “food” and “drug”; many products that formerly would have been classified as drugs, or as both food and drugs, are now considered solely foods.

Various scientific, social, and public health developments combined to precipitate these changes in the law. First, starting in the early 1970s, the medical community and the general public became increasingly interested in the negative health effects of dietary fat, cholesterol, and sodium, and the food industry developed a corresponding desire to take advantage of the science of “negative nutrition” in marketing their products.<sup>314</sup> Second, the 1960s and 70s saw the rise of a craze for the “natural.” American consumers increasingly turned not only to “natural” foods, but also to “natural” remedies, and the growing dietary supplement industry strove to profit from this

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<sup>309</sup> See *infra* Part V.B.

<sup>310</sup> Nutrition and Labeling Education Act (NLEA), Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified in scattered sections of 21 U.S.C. (2000)).

<sup>311</sup> Dietary Supplement Health and Education Act (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified in scattered sections of 21 U.S.C.).

<sup>312</sup> See *infra* Part V.A.

<sup>313</sup> See *infra* Part V.B.

<sup>314</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 79, at 212–14; LEVENSTEIN, *supra* note 167, at 202–12. For a list of prominent reports on diet and health from the 1970s and 1980, see Peter Barton Hutt, *Regulatory Implementations of Dietary Recommendations*, 36 FOOD DRUG COSM. L. J. 66, 67–68 (1981).

trend.<sup>315</sup> Third, many in the antiestablishment-left developed hostility to government intrusion in certain areas, including the field of natural medicines.<sup>316</sup> Fourth, the rise of Reagan Republicanism in the 1980s reflected the increasing influence of a strain of libertarian thought that was generally suspicious of government regulation of commerce, including commercial speech.<sup>317</sup> Finally, the emergence of the AIDS crisis in the 1980s produced a new, highly vocal group of activists who joined cancer victims in insisting on the right to control their own health destinies.<sup>318</sup>

#### A. The NLEA and Disease Prevention Claims

As discussed above, until the mid-1980s, the FDA obstinately stuck to its position that if a food's labeling made a claim regarding a particular disease state, that food was also a drug. In 1984, however, the FTC (which regulates food advertising) not only permitted, but actually lauded, a Kellogg's campaign for All-Bran® cereal that highlighted the relationship between dietary fiber and reduced cancer risk.<sup>319</sup> Discomfited by the inconsistency in the agencies' positions, and under pressure from scientific groups to permit disease prevention claims on food, the FDA reversed course in 1985, publicly stating that it would permit such claims.<sup>320</sup> The FDA then published proposed regulations and an interim enforcement policy that allowed food manufacturers to make disease prevention claims on food, sub-

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<sup>315</sup> See HOOKER, *supra* note 54, at 348–49; LEVENSTEIN, *supra* note 167, at 160–69, 195–200.

<sup>316</sup> See Kathleen M. Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J.L. & MED. 185, 199 (1998) (“[S]ome attribute renewed consumer interest [in alternative medicine] of the 1960s and 1970s to alternative medicine’s reliance on natural remedies and spirituality, which appealed to the anti-establishment . . . counterculture tendencies of the times.”).

<sup>317</sup> See Daniel A. Farber, *Revitalizing Regulation*, 91 MICH. L. REV. 1278, 1278 (1993) (“For the first time since Hoover, a [sitting] president [President Reagan] was actively hostile to the modern administrative state, elected on a platform of ‘less government.’”); Stephen Gardner, *Litigation as a Tool in Food Advertising: A Consumer Advocacy Viewpoint*, 39 LOY. L.A. L. REV. 291, 297–99 (2006) (discussing how “[t]he burgeoning growth of unfounded and illegal claims for foods’ health and nutritional benefits was a prime example of the results of deregulation fever”).

<sup>318</sup> See DAAIR Background, [http://www.im-resource.com/html/sites\\_clients/daair/1\\_daairinfo/1a\\_background.htm](http://www.im-resource.com/html/sites_clients/daair/1_daairinfo/1a_background.htm) (last visited Apr. 10, 2008) (discussing the background of Direct Access Alternative Information Resources (DAAIR), a “not-for-profit buyer’s club and information provider” created in 1991 to enable AIDS and other chronic illness patients to have access to “complementary/alternative treatment”).

<sup>319</sup> See Hutt, *supra* note 135, at 17–20. The FDA disagreed, calling the claims “misleading.” *Id.* at 48.

<sup>320</sup> See *id.* at 48–50; see also HUTT, MERRILL, & GROSSMAN, *supra* note 79, at 284.

ject to certain conditions.<sup>321</sup> The agency confusingly termed these “health claims.”<sup>322</sup>

In 1990, before the FDA could complete its health-claims rulemaking, Congress enacted the NLEA, which explicitly permitted claims characterizing the relationship between a nutrient and “a disease or health-related condition.”<sup>323</sup> The statute amended the FD&C Act to provide that a disease prevention claim may be made with respect to food if the FDA authorizes the claim, by regulation, on the basis of “significant scientific agreement.”<sup>324</sup> The NLEA also amended the FD&C Act’s definition of “drug” to include an exemption for foods with statements made in accordance with the NLEA.<sup>325</sup>

Pursuant to NLEA regulations promulgated in 1993,<sup>326</sup> the FDA has approved petitions for twelve disease claims based on a demonstration of “significant scientific agreement,” including, for example, calcium and osteoporosis, sodium and hypertension, and dietary saturated fat and cholesterol.<sup>327</sup> In 1999, the D.C. Circuit held in *Pearson v. Shalala*<sup>328</sup> that the FDA is obligated under the First Amendment to permit some claims with less than significant scientific agreement if they contain appropriate disclaimers.<sup>329</sup> Four years later, in response to a related subsequent decision by the district court,<sup>330</sup> the FDA embraced a “credible scientific evidence” standard for “qualified” disease claims.<sup>331</sup> The FDA also established a premarket notification process whereby the agency exercises “enforcement discretion” to permit such

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<sup>321</sup> See, e.g., Food Labeling; Health Messages and Label Statements; Reproposed Rule, 55 Fed. Reg. 5176 (Feb. 13, 1990) (codified at 21 C.F.R. pt. 101); Food Labeling; Advance Notice of Proposed Rulemaking, 54 Fed. Reg. 32,610 (Aug. 8, 1989) (codified at 21 C.F.R. pt. 1); Food Labeling; Public Health Messages on Food Labels and Labeling; Notice of Proposed Rulemaking, 52 Fed. Reg. 28,843 (Aug. 4, 1987) (codified at 21 C.F.R. pt. 101).

<sup>322</sup> HUTT, MERRILL & GROSSMAN, *supra* note 79, at 270–71.

<sup>323</sup> Federal Food, Drug, and Cosmetic Act § 403(r)(1)(B), 21 U.S.C. § 343(r)(1)(B) (2000).

<sup>324</sup> *Id.* § 403(r)(3)(B), 21 U.S.C. § 343(r)(3)(B). In 1997, the FD&C Act was further amended to allow disease prevention claims for food affirmed in “authoritative statements” by other federal health agencies or the National Academy of Sciences. *Id.* § 403(r)(3)(C), 21 U.S.C. § 343(r)(3)(C).

<sup>325</sup> *Id.* § 201(g)(1), 21 U.S.C. § 321(g)(1).

<sup>326</sup> See Food Labeling; General Requirements for Health Claims for Food, 58 Fed. Reg. 2478, 2533 (Jan. 6, 1993) (codified at 21 C.F.R. pts. 20, 101).

<sup>327</sup> See 21 C.F.R. §§ 101.72–101.83 (2007).

<sup>328</sup> 164 F.3d 650 (D.C. Cir. 1999).

<sup>329</sup> See *id.* at 658–60; see also *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 8 (D.D.C. 2002) (rejecting the FDA’s initial application of *Pearson*).

<sup>330</sup> *Whitaker*, 248 F. Supp. 2d at 8.

<sup>331</sup> Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (2003) (availability announced 68 Fed. Reg. 41,387, 41,388–89 (July 11, 2003)).

claims if they include obligatory qualifying language that corresponds to the strength of the scientific evidence.<sup>332</sup>

The disease-prevention claims permitted on food do not resemble typical drug claims. Even unqualified claims, approved by the FDA pursuant to a petition, are couched in qualifying language (“*may* reduce the *risk* of”)<sup>333</sup> and presented, as required by the statute, “in the context of a total daily diet.”<sup>334</sup> Nonetheless, the NLEA represented a partial return to an earlier era, in which the labels of both food and drugs explicitly claimed effectiveness against disease, thus blurring the difference between the categories of “food” and “drug.” The NLEA also empowered the FDA to issue regulations authorizing implied disease claims, in the form of standardized statements characterizing the level of nutrients such as fat, cholesterol, sodium, and fiber in food.<sup>335</sup> The resulting nutrient-content-claim regulations contributed to a proliferation of statements such as “low fat” and “cholesterol free” on food labels.<sup>336</sup> The NLEA labeling regime has undoubtedly influenced Americans’ conception of food. As eloquently stated by Michael Pollan:

It was in the 1980s that food began disappearing from the American supermarket, gradually to be replaced by “nutrients,” which are not the same thing. Where once the familiar names of recognizable comestibles—things like eggs or breakfast cereal or cookies—claimed pride of place on the brightly colored packages crowding the aisles, now new terms like “fiber” and “cholesterol” and “saturated fat” rose to large-type prominence. More important than mere foods, the presence or absence of these invisible substances was now generally believed to confer health benefits on their eaters. Foods by comparison were coarse, old-fashioned and decidedly unscientific things—who could say what was in them, really?<sup>337</sup>

The very presence of disease claims on food, along with the atmosphere of chemical reductionism and scientific certainty surrounding

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<sup>332</sup> *Id.*; see also Food Labeling: Health Claims; Dietary Claims: Advance Notice of Proposed Rulemaking, 68 Fed. Reg. 66,040, 66,041 (Nov. 25, 2003) (codified at 21 C.F.R. pt. 101) (seeking comments on alternatives for regulating qualified health claims).

<sup>333</sup> This language appears in all of the approved health claims at 21 C.F.R. See 21 C.F.R. § 101.76(E) (2006); see also HUTT, MERRILL, & GROSSMAN, *supra* note 79, at 294.

<sup>334</sup> Federal Food, Drug, and Cosmetic Act § 403(r)(3)(B)(iii)(ii), 21 U.S.C. § 343(r)(3)(B)(iii)(ii) (2000).

<sup>335</sup> See *id.* § 403(q)(1)(D), (r)(1)(A), (r)(2), 21 U.S.C. § 343(q)(1)(D), (r)(1)(A), (r)(2).

<sup>336</sup> 58 Fed. Reg. 2410, 2410 (Jan. 6, 1993) (codified at 21 C.F.R. § 101.14, 101.54–101.69) (regulating claims about the fat content of foods). The FDA had already commenced the process of defining nutrient descriptors by regulation prior to the 1990 passage of the NLEA. See HUTT, MERRILL, & GROSSMAN, *supra* note 79, at 216–17.

<sup>337</sup> Michael Pollan, *Unhappy Meals*, N.Y. TIMES, Jan. 28, 2007, (Magazine), at 41.

the entire NLEA approach, rendered the difference between food and drugs more indistinct than it was in the pre-NLEA era.<sup>338</sup>

### B. DSHEA: Where's Herb?

Perhaps no class of product presents a starker challenge to the notion of a clear food–drug dichotomy than the herbal and other botanical supplements traditionally used for medicinal purposes. Many of the same herbs used as flavoring agents have also long been used to prevent, treat, or cure disease.<sup>339</sup> Even herbs with unpleasant tastes are taken for remedial purposes in teas.<sup>340</sup> In 1993, the chairman of a U.S. House of Representatives subcommittee sent the following written question to Robert S. McCaleb, the president of the Herb Research Foundation: “To what extent do people consume herbal products for food (e.g., taste, aroma, nutrition) or medicinal purposes?”<sup>341</sup> McCaleb responded:

Herbal products are very diverse in their range of uses. . . . Nearly one-third of [\$1.3 billion in annual retail sales] is composed of herbal teas, which are conventional foods valued for flavor or aroma. The majority of the remaining products are sold in the form of capsules, tablets or liquid extracts. . . . Some of the extracts and all of the capsules and tablets are valued for something other than flavor and aroma. The question of whether the intended effect is nutritional or medicinal depends entirely on definition. . . . [H]erbal supplements in the quantities consumed generally provide little “nutrition” in terms of vitamins, minerals, protein, and so on. However, if we include in the definition of nutrition, substances which protect health or aid in metabolic processes, herbal dietary supplements clearly qualify.<sup>342</sup>

Until the very end of the twentieth century, the FDA seems never to have taken a systematic approach to herbs, botanical products, fish and plant oils, and other “natural” supplement ingredients. Both the regulations approving food additives and the regulations confirming food ingredients as “generally recognized as safe” (GRAS) listed some

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<sup>338</sup> Scientific reductionism and nutritional science are further discussed in Pollan’s article. *See id.* at 44–46.

<sup>339</sup> *See* LEVENSTEIN, *supra* note 53, at 6.

<sup>340</sup> *See infra* note 342 and accompanying text.

<sup>341</sup> Letter from Edolphus Towns, Chairman, H. Subcomm. on Human Res. and Intergovernmental Relations of the H. Comm on Gov’t Operations to Robert S. McCaleb, President, Herb Research Found. (Aug. 3, 1993), in *Food and Drug Administration’s Regulation of Dietary Supplements: Hearing Before the H. Comm. on Government Operations, Subcomm. on Human Res. and Intergovernmental Relations*, 103d Cong. 428 (1994) [hereinafter *July 1993 FDA Hearings*].

<sup>342</sup> Letter from Robert S. McCaleb, President, Herb Research Foundation to Edolphus Towns, Chairman, H. Subcomm. on Human Res. and Intergovernmental Relations of the H. Comm on Gov’t Operations (Aug. 23, 1993), in *July 1993 FDA Hearings*, *supra* note 341, at 430.



herbs.<sup>343</sup> The sellers of many other herbs self-determined their products to be GRAS.<sup>344</sup> The FDA apparently never maintained that herbal products listed in the *USP* or *NF* were automatically drugs,<sup>345</sup> but it almost always treated herbal supplements as drugs if their labeling contained disease claims.<sup>346</sup> Interestingly, however, the agency has long turned a blind eye to traditional Chinese medicine products, even those with explicit disease claims.<sup>347</sup>

Between the early 1980s and the early 1990s, several developments converged to trigger a battle over the regulatory status of herbal supplements.<sup>348</sup> In the 1960s and 1970s, most herbal products were manufactured by small niche companies.<sup>349</sup> These businesses advertised in the alternative press and avoided regulation by frequently changing labels, ingredients, and locations.<sup>350</sup> In the 1980s, however, the natural products business grew rapidly and was increasingly dominated by larger corporations.<sup>351</sup> Herbal products were advertised more widely and became available in grocery stores and drugstores as well as health food and specialty nutrition stores.<sup>352</sup> The herbal supplement industry was thus capable of mounting an organized and well-funded defense if the FDA abandoned its haphazard and largely nonintrusive approach.

The agency did so in the late 1980s, commencing an aggressive enforcement campaign against herbal and other natural supplements, such as evening primrose oil.<sup>353</sup> When such products bore disease claims, the FDA used its drug authorities against them. In the absence of such claims, the agency did not hesitate to employ its food additive powers, even against those supplements that did not obviously provide

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<sup>343</sup> See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,698 (June 18, 1993).

<sup>344</sup> See *id.*

<sup>345</sup> See, e.g., Nat'l Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 337 (2d Cir. 1977) (noting that the FDA does not treat all substances listed in the *USP* and *NF* as drugs, but rather "single[s] out" substances based on other factors).

<sup>346</sup> See, e.g., Kordel v. United States, 335 U.S. 345, 346 (1948) (treating "compounds of various vitamins, minerals and herbs" as drugs when accompanied by pamphlets that made misleading disease claims). The FDA's pre-1994 position regarding the classification of herbal products that made only structure-function claims is difficult to determine, because virtually all of the agency's enforcement actions were against articles making only disease claims or both disease claims and structure-function claims.

<sup>347</sup> HUTT, MERRILL, & GROSSMAN, *supra* note 79, at 619.

<sup>348</sup> See HILTS, *supra* note 187, at 283-84.

<sup>349</sup> See *id.*

<sup>350</sup> See *id.*

<sup>351</sup> See *id.*

<sup>352</sup> See Regulation of Dietary Supplements, 58 Fed. Reg. 33,690, 33,690 (June 18, 1993).

<sup>353</sup> See *F.D.A. in Battle on Health Food Frauds*, N.Y. TIMES, June 1, 1989, at B7.

any “taste, aroma, or nutritive value.”<sup>354</sup> As explained by FDA official Michael Taylor:

[W]e agree that there ought to be an effort to recognize that dietary supplements have attributes that, as a practical matter, place them somewhere between what people think of as foods and what people think of as drugs. But under the current statute we have those two choices to make.<sup>355</sup>

The NLEA of 1990 authorized disease prevention claims (so-called “health claims”) for dietary supplements as well as conventional foods.<sup>356</sup> However, instead of subjecting claims for supplements to the same approval procedure and “significant scientific agreement” standard that the statute established for conventional foods, Congress provided that supplements would “be subject to a procedure and standard, respecting the validity of such claim, established by [FDA regulation].”<sup>357</sup> The FDA, under new Commissioner David Kessler, did not accept the invitation to establish a more liberal standard for dietary supplement claims. Instead, it proposed that disease prevention claims for supplements be subject to the same “significant scientific agreement” standard that applied with respect to conventional foods.<sup>358</sup> This proposal provoked an unprecedented flood of irate mail and telephone calls to the agency and Congress.<sup>359</sup> After a one-year moratorium imposed by Congress,<sup>360</sup> the FDA once again proposed to apply the same approach to health claims for dietary supplements as was used for conventional foods.<sup>361</sup> Congress stepped in

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<sup>354</sup> *Hearing Before the H. Comm. on Government Operations, Subcomm. on Human Res. and Intergovernmental Relations*, 103d Cong. 46–48 (1993) (testimony of Stephen H. McNamara, Counsel, Utah Natural Products Alliance), in *July 1993 FDA Hearings*, *supra* note 341, at 46–48. *But see* *United States v. Two Plastic Drums of . . . Black Currant Oil*, 984 F.2d 814, 815, 820 (7th Cir. 1993) (rejecting the FDA’s assertion that black currant oil was an unapproved food additive when combined solely with the substances used to market it in capsule form). On the origins of the “taste, aroma, or nutritive value” formulation, see *supra* Part IV.

<sup>355</sup> *Hearing of the Comm. on Labor and Human Resources*, 103 Cong. 61 (1993) (statement of Michael Taylor, Deputy Comm’r for Policy, FDA).

<sup>356</sup> Nutrition Labeling and Education Act, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified in scattered sections of 21 U.S.C. (2000)).

<sup>357</sup> Federal Food, Drug, and Cosmetic Act § 403(r)(5)(D), 21 U.S.C. § 343(r)(5)(D) (2000).

<sup>358</sup> Labeling; General Requirements for Health Claims for Food, 56 Fed. Reg. 60,537, 60,539 (Nov. 27, 1991).

<sup>359</sup> *See Hearing Before the H. Comm. on Government Operations, Subcomm. on Human Res. and Intergovernmental Relations*, 103d Cong 72–73 (July 20, 1993) (testimony of Bruce Silverglade, Director of Legal Affairs, Center for Science in the Public Interest), in *July 1993 FDA Hearings*, *supra* note 341, at 72–73; HILTS, *supra* note 187, at 285–86.

<sup>360</sup> *See* Prescription Drug User Fee Act, Pub. L. No. 102-571, 106 Stat. 4491, 4500 (1992).

<sup>361</sup> *See* Food Labeling; General Requirements for Health Claims for Dietary Supplements, 58 Fed. Reg. 33,700 (June 18, 1993) (codified at 21 C.F.R. pt. 101).

again, this time with the Dietary Supplement Health and Education Act of 1994 (DSHEA).

DSHEA created a new regulatory regime for supplements, and, in some ways, significantly reduced the FDA's power over them.<sup>362</sup> The statute formally establishes a new product category of "dietary supplement," which it defines as

a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).<sup>363</sup>

A "dietary supplement" must also be "intended for ingestion" in "tablet, capsule, powder, softgel, gelcap, or liquid form," or in another form if it is "not represented as conventional food and is not represented for use as a sole item of a meal or of the diet."<sup>364</sup> Finally, a "dietary supplement" must be labeled as such.<sup>365</sup>

Several aspects of the regulation of dietary supplements under DSHEA are important to note. First, a dietary supplement is now "deemed to be a food" for most purposes under the FD&C Act, even if it is not a "common sense" food under *Nutrilab*.<sup>366</sup> Second, dietary supplement ingredients are nonetheless excluded from the definition of "food additive."<sup>367</sup> This releases them from the premarket approval requirement applicable to most conventional food ingredients that are not generally recognized as safe.<sup>368</sup> Third, DSHEA excludes supplements that make structure-function claims from the definition of "drug"<sup>369</sup> and thus from the new drug premarket approval requirements. This exclusion applies to all dietary supplements, not just those that are "common sense" foods such as vitamins and miner-

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<sup>362</sup> See Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified in scattered sections of 21 U.S.C. (2000)). But see Peter Barton Hutt, *FDA Statutory Authority to Regulate the Safety of Dietary Supplements*, 31 AM. J. L. & MED. 155, 157 (contending, with respect to safety regulation, that "on balance the FD&C Act, as amended by DSHEA, provides somewhat greater FDA regulatory authority over dietary supplements than over conventional food").

<sup>363</sup> *Id.* § 3(a), 108 Stat. at 4327 (codified at 21 U.S.C. § 321(ff)(1) (2000)).

<sup>364</sup> *Id.* (codified at 21 U.S.C. § 321(ff)(2)) (incorporating this list of forms by reference to Federal Food, Drug, and Cosmetic Act § 411(c)(1)(B)(i)-(ii), 21 U.S.C. § 350(c)(1)(B)(i)-(ii)).

<sup>365</sup> *Id.* (codified at 21 U.S.C. § 321(ff)(2)(C)).

<sup>366</sup> *Id.* (codified at 21 U.S.C. § 321(ff)).

<sup>367</sup> *Id.* § 3(b) (codified at 21 U.S.C. § 321(s)(6)).

<sup>368</sup> The food additive petition and approval process is set forth at Federal Food, Drug, and Cosmetic Act § 409(b), (c), 21 U.S.C. § 348(b), (c) (2000 & Supp. V 2005).

<sup>369</sup> See § 3(a), 108 Stat. at 4327 (codified at 21 U.S.C. § 321(g)(1)).

als.<sup>370</sup> However, instead of simply relying on the parenthetical food exception from the structure-function branch of the drug definition, DSHEA added a new section significantly titled “Statements of *Nutritional* Support.”<sup>371</sup> This section requires a supplement manufacturer, unlike a conventional food manufacturer, to have “substantiation” of a structure-function claim, to accompany the statement with a prominent disclaimer, and to notify the FDA of its use of the claim within 30 days after the commencement of marketing.<sup>372</sup> Although the legislative process leading to the enactment of DSHEA was triggered largely by controversy over the FDA’s refusal to create a separate NLEA health claims procedure for dietary supplements,<sup>373</sup> the enacted statute did not require the FDA to do so. To date, the agency, using a process equivalent to that used for conventional foods,<sup>374</sup> has approved only two unqualified health claims for dietary supplements.<sup>375</sup>

Denied the right to liberally communicate the benefits of their products through disease prevention claims (health claims),<sup>376</sup> supplement manufacturers turned instead to structure-function claims. Before 1994, there was no hint of how creatively such claims could be used. After the enactment of DSHEA, the dietary supplement industry re-imagined structure-function claims, expanding them well beyond the “helps weight loss” and “builds strong bones” statements that had occasionally been used with conventional foods.<sup>377</sup> St. John’s

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<sup>370</sup> See *Nutrilab Inc. v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983).

<sup>371</sup> § 6, 108 Stat. at 4329 (codified at 21 U.S.C. § 343(r)(6)) (emphasis added). This section of DSHEA appears at Federal Food, Drug, and Cosmetic Act § 403(r)(6), without the title “Statements of Nutritional Support.”

<sup>372</sup> See *id.* The mandatory disclaimer states: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” *Id.* § 6, 108 Stat. at 4329 (codified at 21 U.S.C. § 343(r)(6)(C)).

<sup>373</sup> See generally Meghan Colloton, Comment, *Dietary Supplements: A Challenge Facing the FDA in Mad Cow Disease Prevention*, 51 AM. U. L. REV. 495, 512–24 (2002) (offering a historical perspective on the struggle that led to DSHEA’s enactment).

<sup>374</sup> See Dietary Supplements; Comments on Report of the Commission on Dietary Supplement Labels, 63 Fed. Reg. 23,633, 23,634 (Apr. 29, 1998) (“The [FD&C Act] provides that FDA may authorize a health claim for a conventional food only if the agency determines . . . ‘that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.’”) (quoting Federal Food, Drug, and Cosmetic Act § 403(r)(3)(B)(i), 21 U.S.C. 343 § (r)(3)(B)(i)).

<sup>375</sup> See Health Claims: Calcium and Osteoporosis, 21 C.F.R. § 101.72 (2007) (permitting claim that calcium may reduce the risk of osteoporosis); Health Claims: Folate and Neural Tube Defects, 21 C.F.R. § 101.79 (2007) (permitting claim that folate may reduce the risk of neural tube defects).

<sup>376</sup> See generally Dana Ziker, *Regulating Functional Foods: Pre- and Post-Market Strategy*, 2002 DUKE L. & TECH. REV. 0024 (2002), available at <http://www.law.duke.edu/journals/dltr/articles/2002dltr0024.html> (describing the ongoing battle between the FDA and an ever-evolving food industry).

<sup>377</sup> See CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, FDA, CLAIMS THAT CAN BE MADE FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (2003), <http://www.cfsan.fda.gov/>

Wort, used overseas as a remedy for depression, might be labeled "Promotes Positive Mood & Healthy Emotional Balance." Saw Palmetto, a well-known European treatment for enlarged prostate, might claim "Supports Healthy Prostate Function." The FDA endorsed just such an approach in its DSHEA regulations, allowing the use of terms such as "stimulate," "maintain," "support," "regulate," and "promote."<sup>378</sup> The agency also ruled that statements concerning nonserious "natural life state" conditions, such as noncystic acne, morning sickness, hot flashes, and mild geriatric memory loss, were permissible subjects of structure-function claims.<sup>379</sup> Grocery and drugstore shelves are now filled with dietary supplements that make structure-function claims with a wink at consumers interested in using them to fight disease.

DSHEA dramatically expands the legal category of "food" far beyond *Nutrilab's* "common sense" notion of articles used primarily for taste, aroma, or nutritive value. Vitamin and mineral pills, which were treated as food even before DSHEA, have indisputable nutritive value.<sup>380</sup> By contrast, many of the amino acids, herbs, and botanicals that are now classified as "food" by DSHEA do not have significant nutritive value, at least in the traditional sense of the term "nutritive." Moreover, DSHEA encompasses concentrates, metabolites, constituents, and extracts of each of these ingredients.<sup>381</sup> The statute thus challenges the common cultural understanding of "food" and further obscures the distinction between "food" and "drugs." Today, a capsule containing the extract of a foul-tasting herb, sold in a pill bottle with barely disguised disease claims on its label is, for legal purposes, a "food." At the beginning of this story, such a product was a prototypical drug.

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~dms/hclaims.html (explaining possible structure-function relationships between a nutrient and its purported function).

<sup>378</sup> See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,625 (proposed Apr. 29, 1998) (codified at 21 C.F.R. pt. 101).

<sup>379</sup> Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000, 1020 (Jan. 6, 2000) (to be codified at 21 C.F.R. pt. 101). For a complete list of the claims explicitly permitted or forbidden in the preamble to the final rule, see HUTT, MERRILL, & GROSSMAN, *supra* note 79, at 282. Shortly after issuing this rule, FDA advised that "natural life state" claims should not be made with respect to conditions associated with pregnancy, such as morning sickness, because of the risks that dietary supplements might pose to unborn children. Statement, Dep't of Health and Human Servs., FDA Statement Concerning Structure/Function Rule and Pregnancy Claims (Feb. 9, 2000), <http://www.fda.gov/bbs/topics/NEWS/NEW00715.html>.

<sup>380</sup> See *infra* notes 391–97 and accompanying text.

<sup>381</sup> See Federal Food, Drug, and Cosmetic Act § 201 (ff)(1)(F), 21 U.S.C. § 321(ff)(1)(F) (2000).

But does DSHEA really expand the category of “food,” or does it establish a distinct intermediate category? In drafting the statute, Congress seemed to recognize the limits of its power to reshape cultural concepts. Instead of simply adding dietary supplements to the statutory definition of “food,” DSHEA defines them separately and provides that they are “deemed to be a food” for most regulatory purposes.<sup>382</sup> Furthermore, DSHEA and its regulations impose certain unique requirements on dietary supplements that perpetuate the cultural understanding that supplements are different from conventional foods.<sup>383</sup> For example, dietary supplement labels bear a boldly titled “Supplement Facts” box, rather than the “Nutrition Facts” box that appears on conventional foods.<sup>384</sup> Moreover, as noted above, structure-function claims on dietary supplements must be accompanied by a prominent disclaimer that is not required for conventional foods.<sup>385</sup>

In fact, DSHEA seems to have helped forge a new product category in everyday vernacular. In 1989, five years before the enactment of the statute, the term “dietary supplement” appeared in a nonlegal context in only 29 articles in a database of 12 major American newspapers.<sup>386</sup> In 1999, the corresponding number was 186, and by 2003 it was 310.<sup>387</sup> Moreover, by legally grouping vitamin-mineral products with herbal and botanical supplements, DSHEA helped link them in the popular consciousness. In 1989, 17 articles in the same database mentioned “vitamin” or “mineral” within five words of “herbal” or “botanical.”<sup>388</sup> By 1999, that number was 75.<sup>389</sup> This trend was no doubt helped along by the fact that in the late 1990s, the makers of Centrum and One-A-Day vitamins took advantage of the commercial opportunities created by DSHEA and started selling herbal products under the same brand names.<sup>390</sup>

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<sup>382</sup> *Id.* § 201(f), (ff), 21 U.S.C. § 321(f), (ff).

<sup>383</sup> *See supra* notes 362–75 and accompanying text.

<sup>384</sup> *Compare* Nutrition Labeling of Dietary Supplements, 21 C.F.R. 101.36(e) (2007) (setting forth the “Supplement Facts” requirements for dietary supplements), *with* Nutrition Labeling of Food, 21 C.F.R. § 101.9(d) (2007) (setting forth the “Nutrition Facts” requirements for conventional foods).

<sup>385</sup> *See supra* notes 372 and accompanying text.

<sup>386</sup> LEXIS search of 12 major U.S. newspapers (Mar. 10, 2008) (author’s self-constructed database includes newspapers that have been fully searchable on Lexis since at least Jan. 1, 1989) (search terms: <“dietary supplement” and not (Congress or FDA or “food and drug administration” or law or statute)>) (date restricted to 1989).

<sup>387</sup> *Id.* (date restricted to 1999); *id.* (date restricted to 2003).

<sup>388</sup> *Id.* (search terms: <(vitamin or mineral) w/5 (herbal or botanical)>) (date restricted to 1989).

<sup>389</sup> *Id.* (date restricted to 1999).

<sup>390</sup> *See* Michael Wilke, *Bayer Boosts One-A-Day with Herbal Supplements*, ADVERTISING AGE, July 20, 1998, at 4; *Whitehall’s Centrum Herbals Six Product-Line Launching Mid-November*, 6 TAN SHEET, Oct. 26, 1998, at 16.

### C. “Nutritive Value”

Because the “common sense” definition of food is an article used primarily for its “taste, aroma, or nutritive value,” the breadth of the category depends largely on the meaning of “nutritive value.” In recent years, the FDA has suggested that “nutritive value” might be a surprisingly expansive concept.

The agency first started wrestling with the meaning of “nutritive value” after the passage of the NLEA. The FDA’s health claims regulations, finalized in 1993, stated that to be eligible for a health claim, a substance must “contribute taste, aroma, or nutritive value, or any other technical effect listed in [§] 170.3(o) to the food.”<sup>391</sup> The rule also provided that “[*n*] *utritive value* means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.”<sup>392</sup> The FDA explained that its use of the phrase “such processes as” conveyed “a measure of flexibility that . . . is necessary for evaluating future [health claims] petitions. . . . [T]here may be a wide array of substances that could logically supply nutritive value.”<sup>393</sup>

In 1994, when the FDA applied the same health claims requirements to dietary supplements, it once again stressed the flexibility of the phrase “nutritive value.”<sup>394</sup> To provide some guidance, the agency stated that in assessing whether a substance provides nutritive value, “[i]n general, the agency will look for evidence that the claimed effect on disease is associated with the normal maintenance of human existence.”<sup>395</sup> The FDA denied requests that it revise the definition of “nutritive value” to embrace disease prevention generally, because “the relationship between a food or a food component to a disease is quite different from that of a drug. . . . [I]t has proved difficult to demonstrate causal associations between specific dietary factors and chronic or other diseases.”<sup>396</sup> This was only a question of semantics, however, for the FDA has approved various “health claims” that indisputably correlate the increased consumption of particular dietary substances with a reduced risk of particular diseases.<sup>397</sup>

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<sup>391</sup> Food Labeling; General Requirements for Health Claims for Food, 58 Fed. Reg. 2478, 2533 (Jan. 6, 1993) (codified at 21 C.F.R. § 101.14(b)(3)(1)).

<sup>392</sup> *Id.* (codified at 21 C.F.R. § 101.14(a)(3) (emphasis added)).

<sup>393</sup> *Id.* at 2478 (codified at 21 C.F.R. pts. 20 & 101).

<sup>394</sup> Food Labeling; General Requirements for Health Claims for Dietary Supplements, 59 Fed. Reg. 395, 407 (proposed Jan. 4, 1994) (codified at 21 C.F.R. pts. 20 & 101).

<sup>395</sup> *Id.*

<sup>396</sup> *Id.*

<sup>397</sup> See, e.g., Health Claims: Calcium and Osteoporosis, 21 C.F.R. § 101.72 (1997) (describing how calcium helps to reduce the risk of osteoporosis); Health Claims: Soy Protein and Risk of Coronary Heart Disease (CHD), 21 C.F.R. § 101.82(a)(3) (1999) (“[T]he addition of soy protein to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.”).

In 2000, the FDA demonstrated how far it is willing to stretch the notion of “nutritive value” when it approved health claims petitions filed by the manufacturers of two cholesterol-lowering bread spreads (Take Control and Benecol). The beneficial effect of these products was due to the presence of plant sterol esters in the former and plant stanol esters in the latter. These substances apparently lower cholesterol by preventing the absorption of cholesterol into the intestines.<sup>398</sup> Having already declined to challenge the manufacturers’ self-determination that plant sterol/stanol esters were GRAS,<sup>399</sup> the FDA authorized health claims about the role of these substances in reducing the risk of coronary heart disease (CHD).<sup>400</sup> Since plant sterol/stanol esters clearly did not contribute taste, aroma, or a § 170.3(o) technical effect to food, the FDA resorted to stating that they contributed “nutritive value.”<sup>401</sup> It reasoned: “The scientific evidence suggests that the cholesterol-lowering effect of plant sterol esters is achieved through an effect on the digestive process. . . . The digestive process is one of the metabolic processes necessary for the normal maintenance of human existence.”<sup>402</sup>

The FDA’s assertion that plant sterol/stanol esters contribute “nutritive value” is remarkable. These substances do not act by being incorporated into the body, but by *preventing* the absorption of cholesterol into the body. In *Nutrilab*—the source of the “taste, aroma, or nutritive value” test—the court considered it so obvious that starch blockers did not contribute “nutritive value” that it did not even bother to explain its basis for this conclusion.<sup>403</sup> Yet starch blockers allegedly controlled weight by preventing the absorption of starch,<sup>404</sup> just as plant sterol/stanol esters reduce the risk of CHD by preventing the absorption of cholesterol. If in the 1980s, the FDA had applied the same reasoning to starch blockers that it applied to Benecol twenty years later, the agency would have concluded that starch blockers were, in fact, common-sense foods. In approving the plant sterol/stanol ester petitions, the agency embraced a notion of “nutritive value” so expansive that it could potentially apply to any drug ingested for disease prevention.

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<sup>398</sup> See Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease, 65 Fed. Reg. 54,686, 54,690–700 (Sept. 8, 2000) (codified at 21 C.F.R. pt. 101).

<sup>399</sup> See *id.* at 54,688–89.

<sup>400</sup> *Id.* at 54,717–19.

<sup>401</sup> See *id.* at 54,688.

<sup>402</sup> *Id.*

<sup>403</sup> See *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983); see also *United States v. Undetermined Quantities of “Cal-Ban 3000,”* 776 F. Supp. 249, 255 (E.D.N.C. 1991) (finding that a starch-blocker product was not used for nutritive value because “advertisements make it clear that a person who chooses to ingest Cal-Ban would be doing so to prevent nutrition from entering the body, rather than to allow it”).

<sup>404</sup> See *Nutrilab*, 713 F.2d at 336.



## CONCLUSION: "DROODS"

The history recounted in this article suggests that legal definitions of basic-level cultural categories like "food" and "drug" will never result in bright lines, in part because the cultural categories themselves are strikingly imprecise and malleable. Moreover, my research suggests that although cultural categories inevitably shape and blur corresponding legal categories, legal categories in turn can play a powerful role in molding cultural conceptions. In short, the story of the legal and cultural notions of "food" and drug" is one of synergistic interaction.

To further understand this symbiotic process at work, consider the following hypothetical scenario: Congress amends the FD&C Act to create a new category called "droods," encompassing all articles (whether presently "food" or "drugs") that are "intentionally ingested by man." The amendments also establish a unified regulatory system applicable to all droods. To sell a drood legally, a manufacturer must either determine that the drood is GRAS or obtain FDA premarket approval of an application, similar to a food additive petition, showing a "reasonable certainty of no harm."<sup>405</sup> The manufacturer of a drood claiming to diagnose, cure, mitigate, or treat a disease must, unless the drood is generally recognized as effective, acquire premarket approval of an NDA-like application setting forth "substantial evidence" of effectiveness.<sup>406</sup> A drood making a disease *prevention* claim, by contrast, can enter the market if the agency approves a premarket application, akin to a health claims petition, demonstrating that there is "significant scientific agreement" in support of the claim.<sup>407</sup> Finally, structure-function claims for droods are not subject to any premarket review; the FDA will police them using its traditional enforcement powers against misbranding.

What, if anything, is wrong with this scheme? Do the flaws, if any, derive from the elimination of the legal distinction between "food" and "drug?" Could the proposal be successfully implemented in our

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<sup>405</sup> See S. REP. NO. 2422, at 5301 (1958) (describing the standard used for food additive petitions). To protect the public against inaccurate or fraudulent self-determinations of GRAS status, this hypothetical regime could require manufacturers to provide the FDA with premarket notification of all "new" drood ingredients and further mandate that this notification set forth the manufacturer's basis for concluding that the ingredient is GRAS. A similar requirement currently applies to "new dietary ingredients" in dietary supplements. Federal Food, Drug, and Cosmetic Act § 413(a), (c), 21 U.S.C. § 350b(a), (c) (2000).

<sup>406</sup> Federal Food, Drug, and Cosmetic Act § 505(d), 21 U.S.C. § 355(d) (providing the standard used for approval of new drugs). The statutory scheme could, of course, require that drood manufacturers present their evidence of safety and their evidence of effectiveness in a single premarket application.

<sup>407</sup> *Id.* § 403(r)(3)(B), 21 U.S.C. § 343(r)(3)(B) (providing the standard used for health claims).

society, which has long viewed “food” and “drug” as different, though overlapping, categories? Would the very institution of such an approach eventually forge “dood” into a cultural category that Americans could accept as the organizing concept of a regulatory scheme? While this article does not offer a definitive answer to any of these questions, I hope it has provided some dood for thought.