

## NUTRITION LABELING: FDA REGULATION OF CLAIMS OF THERAPEUTIC VALUE IN FOOD PRODUCT LABELING

In 1973 the Commissioner of the Food and Drug Administration (FDA) promulgated food labeling regulations<sup>1</sup> to provide more informative nutrition labeling of food products in response to evidence that most Americans were not receiving adequate nutrition in their daily diets.<sup>2</sup> Under the regulations, nutrition labeling is voluntary

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1. 21 C.F.R. § 1.17 (1973). These regulations were proposed in 37 Fed. Reg. 6493 (1972). *See also* 38 Fed. Reg. 2125-32, 6950-61 (1973).

2. *See* 37 Fed. Reg. 6493-94 (1972); WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, FINAL REPORT 295-98 (1970) (recommending adoption of a uniform system of nutrition labeling to give consumers information on balancing their daily diets). Information presented at the conference documented the existence of malnutrition in at least 30 million of the U.S. population. 24 FOOD TECHNOLOGY 866 (1970). In a special message to Congress on consumer problems President Kennedy stated:

Consumer choice is influenced by mass advertising utilizing highly developed arts of persuasion. The consumer typically cannot know . . . whether one prepared food has more nutritional value than another; whether the performance of a product will in fact meet his needs. . . . [T]he responsibility of the Government in protecting the consumer is increasingly recognized. 108 CONG. REC. 4167, 4168 (1962).

The President stated four basic rights of the consumer: (1) the right to safety, (2) the right to be informed—to be protected against fraudulent, deceitful or grossly misleading information, advertising, labeling or other practices, and to be given the facts needed to make an informed choice, (3) the right to choose, and (4) the right to be heard. He asked Congress and every appropriate agency to enact legislation to protect the consumer interest and to promote the fuller realization of these consumer rights. *Id.* at 4168. Recognition of this need resulted in increased pressure within Congress to develop more informative nutrition labeling requirements. *See, e.g.*, H.R. 3702, 93d Cong., 1st Sess. (1973) (bill to enact Nutritional Labeling Act of 1973); S. 322, 93d Cong., 1st Sess. (1973) (bill to amend the Fair Packaging and Labeling Act to provide for the establishment of national standards for nutrition labeling of food commodities). The Commissioner of the FDA responded by promulgating the nutrition labeling regulations to “provide consumers with information at the points of purchase and use to compare products, to evaluate nutritional claims which have been made for a product, and to prepare a nutritious diet.” 38 Fed. Reg. 6952 (1973). The regulations provide that if nutrition information labeling is required, a listing of seven important vitamins and minerals must ordinarily be included on the label (vitamins A and C, thiamin, riboflavin, niacin, calcium and iron), and that whenever a food is labeled with nutrition information, the label must follow a standard established format (including statements of serving size, servings per container, caloric content, protein content, carbohydrate content, fat content, and percentage

for most foods, but full nutrition information labeling is required if a nutrient is added to a product, even to replace those lost in processing, or if a statement claiming nutritive value is made for the food in labeling or advertising.<sup>3</sup> The regulations prohibit certain claims, deemed inherently misleading, from appearing on the labels of food products and supplements.<sup>4</sup> This Comment examines the background, legality and implications of a regulation, section 1.17(h)(9)(i), which provides that:

A food labeled under the provisions of this section shall be deemed to be misbranded . . . if its labeling represents, suggests, or implies:

(1) That the food because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom.<sup>5</sup>

Legislative control of false or misleading therapeutic statements in advertising and labeling was inadequate prior to 1938.<sup>6</sup> In that year,

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of U.S. Recommended Daily Allowances). *Id.* at 6959-60. The regulations also change the standard for levels of vitamins and minerals from "outmoded" FDA Minimum Daily Requirements to a percentage of U.S. Recommended Daily Allowances (U.S. RDA), allows consumers to identify foods for inclusion in physician-recommended fat modified diets (labeling for cholesterol and fats), and classifies products containing vitamins and minerals into three basic categories according to the percentage of U.S. RDA—food products (less than 50% of U.S. RDA), dietary supplements (from 50% to 150%), and drugs (greater than 150%).

3. *See id.* at 2125. Such claims would be confusing and misleading for lack of completeness and could deceive consumers about the food's true nutritional contribution in the daily diet. *Id.*

4. 21 C.F.R. § 1.17 (1973) (food products); 38 Fed. Reg. 20718 (1973) (foods for special dietary use under 21 C.F.R. § 125.2). These regulations prohibit any claim or promotional suggestion that: (1) food products or supplements are sufficient in themselves to prevent, treat or cure disease or symptoms; (2) a balanced diet of ordinary foods cannot supply adequate nutrients; (3) inadequate or insufficient daily diet is due to the soil in which food is grown; (4) transportation, storage, processing or cooking of foods may result in an inadequate or deficient daily diet; (5) the food has dietary properties when such properties have no significant value or need in human nutrition (*i.e.*, contains rutin, other bioflavonoids, inositol and similar ingredients); (6) a natural vitamin in food is superior to an added or synthetic vitamin.

5. 21 C.F.R. § 1.17(h)(9)(i) (1973). This Comment examines only the question of the Commissioner's power under the Food, Drug, and Cosmetic Act and does not address any constitutional questions that might be raised with respect to the regulation.

6. Following the turn of the century there was a great increase in the use of fraudulent therapeutic claims in the sale of proprietary medicines. The Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, failed to provide adequate control over these claims. In 1911 the Supreme Court ruled in *United States v.*

however, the Federal Food, Drug, and Cosmetic Act<sup>7</sup> declared that food products with labels bearing claims "misleading in any particular"<sup>8</sup> constituted misbranded products in violation of the Act<sup>9</sup> without regard to fraudulent intent.<sup>10</sup> Under this statute, the Food and Drug Administration successfully brought numerous actions to prevent these promotional practices.<sup>11</sup> Nevertheless, because of the inherent weaknesses of the adjudicative process<sup>12</sup>—lack of clearly articulated standards and increased expense and delay in controlling the prescribed conduct—manufacturers and distributors continued to use such claims.<sup>13</sup> The Commissioner promulgated section 1.17(h)(9)(i) to

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Johnson, 221 U.S. 488 (1911), that the term "misbranded" did not apply to label statements of curative value but only to statements of identity, strength, quality and purity. One year later Congress passed the Sherley Amendment, ch. 352, 37 Stat. 416 (1912), which expanded the meaning of "misbranding" to include false and fraudulent statements concerning therapeutic effects. The Government, however, was faced with the difficult task of proving fraudulent intent. The Depression aggravated the evils of false therapeutic promises. After the Wheeler-Lea Act, ch. 49, 52 Stat. 111 (1938), was passed, giving the FTC regulatory power over advertising of food and drugs, the Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040, was signed into law. *See generally* Ohi, *New Food and Drug Legislation*, 4 JOHN MARSHALL L.Q. 1 (1938); Young, *The Government and the Consumer: Evolution of Food and Drug Laws—The 1938 Food, Drug, and Cosmetic Act*, 13 J. PUB. L. 197 (1964); *Developments in the Law: The Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632 (1954).

7. 21 U.S.C. §§ 301, 321 *et seq.* (1970).

8. *Id.* § 343(a). *See also id.* §§ 352(a), 362(a) (drugs and cosmetics).

9. *Id.* § 331(a) (prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is . . . misbranded").

10. *Compare* *People v. Beggs*, 69 Cal. App. 2d 819, 160 P.2d 600 (Dist. Ct. App. 1945) (knowledge or intent to defraud not required under 1938 Act) *with* *Seven Cases v. United States*, 239 U.S. 510 (1915) (1906 Act required intent to deceive).

11. *E.g.*, *Kordel v. United States*, 335 U.S. 345 (1948); *United States v. Vitasafe Corp.*, 345 F.2d 864 (3d Cir. 1965); *United States v. "Cal's Tupelo Blossom U.S. Fancy Pure Honey,"* 344 F.2d 288 (6th Cir. 1965); *V.E. Irons, Inc. v. United States*, 244 F.2d 34 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957); *United States v. Hohensee*, 243 F.2d 367 (3d Cir.), *cert. denied*, 353 U.S. 976 (1957). The Federal Trade Commission's orders prohibiting similar misleading promotional practices have also been upheld. *See, e.g.*, *S.S.S. Co. v. FTC*, 416 F.2d 226 (6th Cir. 1969); *J.B. Williams Co. v. FTC*, 381 F.2d 884 (6th Cir. 1967).

12. *See* note 17 *infra*.

13. *See* 38 Fed. Reg. 6958 (1973), *citing* cases listed in note 21 *infra*.

strengthen governmental control over misleading labeling of food products and supplements.<sup>14</sup> In shifting from an adjudicative to a rule-making approach, the Commissioner recognized<sup>15</sup> that the choice between proceeding by quasi-legislative rule-making or by ad hoc litigation lies primarily in the informed discretion of the administrative agency,<sup>16</sup> and that "the particularization of a statute by rule-making is not only acceptable in lieu of protracted piecemeal litigation . . . but it is the preferred procedure . . ."<sup>17</sup>

#### I. THE AUTHORITY OF THE FDA TO PROHIBIT CLAIMS OF THERAPEUTIC VALUE IN FOOD PRODUCT LABELING

In January 1973, following the issuance of a tentative order promulgating the nutrition labeling regulations, the Commissioner allowed interested persons to file written exceptions with the Commissioner, challenging his authority under the 1938 Act to adopt regulations prohibiting statements of therapeutic value from appearing on the labels of food products and supplements.<sup>18</sup> To justify these prohibi-

14. 38 Fed. Reg. 6958 (1973). The Commissioner concluded:

[R]eliance upon scare promotional claims, designed to panic the public into believing that nutrient fortification or supplementation is necessary to prevent the onset of severe deficiency diseases, is neither supported by the available scientific and medical facts nor fosters good nutritional practices.

*Id.*

15. *See id.* at 6951.

16. *See* SEC v. Chenery Corp., 332 U.S. 194, 203 (1947).

17. *Ciba-Geigy Corp. v. Richardson*, 446 F.2d 466, 468 (2d Cir. 1971). *See generally* Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy*, 78 HARV. L. REV. 921 (1965). In *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 681 (D.C. Cir. 1973), the court stated:

[T]here is little question that the availability of substantive rule-making gives any agency an invaluable resource-saving flexibility in carrying out its task of regulating parties subject to its statutory mandate. More than merely expediting the agency's job, use of substantive rule-making is increasingly felt to yield significant benefits to those the agency regulates. Increasingly, courts are recognizing that use of rule-making to make innovations in agency policy may actually be fairer to regulated parties than total reliance on case-by-case adjudication.

A justification for the rule-making procedure is expressed in K. DAVIS, *ADMINISTRATIVE LAW TEXT* 151 (3d ed. 1972):

One fundamental probability is that nearly all businessmen comply nearly all the time with law that is clear, but when their lawyers don't know what the law requires they often go ahead with whatever practices maximize profits. The way to create administrative activity that will be expensive . . . is to keep the law unclear. And the way to keep the law unclear is to do nothing to clarify it except to bring prosecutions and to work out some conflicting case law.

18. *See* 38 Fed. Reg. 2143 (1973). *See also id.* at 6396, 6951, 20710.

tions, the Commissioner relied on section 371 (a) of the Act (which gives the Commissioner the authority to promulgate regulations for the efficient enforcement of the Act),<sup>19</sup> various other sections of the Act dealing specifically with the problem of misbranded foods,<sup>20</sup> and several judicial decisions upholding the promulgation of rules on the basis of similar statutory authority.<sup>21</sup> It appears the Commissioner was correct in his assertion that the promulgation of these specific provisions of the 1973 regulation did not exceed his authority under the 1938 Act.

The validity of a regulation promulgated under section 371 (a), the empowering provision of the Food, Drug, and Cosmetic Act, will be sustained as long as it is reasonably related to the purposes of the enabling legislation.<sup>22</sup> The application of this "reasonable relationship" standard is illustrated by the Supreme Court's decision in *United*

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19. 21 U.S.C. § 371(a) (1970). The statute itself gives this power to the Secretary of HEW. This power, however, was redelegated to the Commissioner. 21 C.F.R. § 2.120 (1973).

20. 21 U.S.C. § 321(n) (1970) (reproduced in note 31 *infra*); *id.* § 343(a) (false and misleading labeling); *id.* § 343(j) (representation for special dietary use). *See generally* 38 Fed. Reg. 2124, 20710 (1973).

21. 38 Fed. Reg. 6951 (1973). Specifically, the Commissioner relied on *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967) (regulations issued by the Commissioner have the force of law and the district court has jurisdiction to undertake pre-enforcement review of the regulation); *FPC v. Texaco, Inc.*, 377 U.S. 33 (1964) (upheld regulation establishing "permissible" pricing provisions in contracts of natural gas producers and stating that any contract containing other provisions shall be rejected); *United States v. Storer Broadcasting Co.*, 351 U.S. 192 (1956) (FCC's maximum station ownership regulation upheld and found to have force of law with respect to ripeness for review); *SEC v. Chenery Corp.*, 332 U.S. 194 (1947); *Ciba-Geigy Corp. v. Richardson*, 446 F.2d 466 (2d Cir. 1971) (Commissioner of FDA has power to issue binding interpretive regulations requiring that a new drug applicant present "substantial evidence" of effectiveness before being given an opportunity for a hearing). In *FPC v. Texaco, Inc.*, 377 U.S. 33 (1964), the Court held that the statutory requirement of a hearing did not preclude the Commissioner from particularizing statutory standards through the rulemaking power.

22. *See Mourning v. Family Publications Serv., Inc.*, 411 U.S. 356 (1973). In *Mourning* the "Four Installment Rule" was promulgated under an empowering provision providing that the agency may make "such rules and regulations as may be necessary to carry out the provisions of the Act." The Court held that the Rule was not promulgated in excess of the Federal Reserve Board's authority, was reasonably related to its objectives, and was not inconsistent with the Truth in Lending Act. *Id.* *See also* *National Broadcasting Co. v. United States*, 319 U.S. 190 (1943).

*States v. Storer Broadcasting Co.*,<sup>23</sup> upholding a regulation of the Federal Communications Commission (FCC) against a claim that promulgation of the regulation exceeded the Commission's authority under the Federal Communications Act of 1934.<sup>24</sup> The Court reasoned that the FCC, dealing with the public interest and operating under a statute designed to protect the public, had broad powers to promulgate a maximum station ownership regulation. The regulation was held reconcilable with the purpose of the Federal Communications Act as a whole.<sup>25</sup> This reasoning would also seem to justify the FDA's prohibition of claims of therapeutic value in labeling.

The Federal Food, Drug, and Cosmetic Act is designed to protect the health<sup>26</sup> and economic interests<sup>27</sup> of consumers, who, under present conditions, are largely unable to protect themselves in this field.<sup>28</sup> The Act is aimed not only at false and fraudulent claims, but also at clever indirection, ambiguity<sup>29</sup> and exaggerated or overemphasized state-

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23. 351 U.S. 192 (1956).

24. 47 U.S.C. § 151 *et seq.* (1970).

25. The Court in *Storer Broadcasting Co.* stated: (1) the Commission deals with the public interest; (2) Congress sought to create regulation for public protection; (3) the growing complexity of the economy induced Congress to put the regulation of business in specialized agencies with broad powers; (4) the courts are slow to interfere with the agency's conclusions when reconcilable with statutory directive; and (5) the rules were reconcilable with the act as a whole. 351 U.S. at 203-04. The justification of a regulation depends on the statutory scheme as a whole. *See Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 163 (1967).

26. *United States v. "Cal's Tupelo Blossom U.S. Fancy Pure Honey,"* 344 F.2d 288, 289 (6th Cir. 1965); *United States v. Omar, Inc.*, 91 F. Supp. 121, 123 (D. Neb. 1950).

27. *United States v. Article . . . Consisting of 216 Cartoned Bottles*, 409 F.2d 734 (2d Cir. 1969); *United States v. Three Cartons*, 132 F. Supp. 569 (S.D. Cal. 1952); *United States v. 30 Cases*, 93 F. Supp. 764 (S.D. Iowa 1950) (the purpose is not the protection of merchants and traders but rather of the consumer public).

28. *United States v. Vitasafe Corp.*, 345 F.2d 864, 870 (3d Cir. 1965). The Supreme Court has stated:

The purposes of this legislation . . . "touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government . . . ."

62 *Cases of Jam v. United States*, 340 U.S. 593, 596 (1951), quoting *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

29. *V.E. Irons, Inc. v. United States*, 244 F.2d 34 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957); *United States v. One Device*, 160 F.2d 194 (10th Cir. 1947). *See also United States v. 95 Barrels of Vinegar*, 265 U.S. 438 (1924) (under 1906 Act).

ments or representations.<sup>30</sup> The terms of the statute condemn every statement, design or device that may mislead or deceive, and it has been held that deception may result from the use of statements technically correct but misleading in total impression.<sup>31</sup>

Under the Act, false or misleading labeling is "measured by its significance as read by those to whom it appeals."<sup>32</sup> The determining factor is the attraction of the statements to the average person<sup>33</sup>—to people of ordinary understanding and discrimination.<sup>34</sup> The courts have rejected the contention that the test should be the significance

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30. *United States v. Vitasafe Corp.*, 345 F.2d 864 (3d Cir. 1965); *V.E. Irons, Inc. v. United States*, 244 F.2d 34 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957).

31. *United States v. 95 Barrels of Vinegar*, 265 U.S. 438 (1924) (under 1906 Act); *Taylor v. United States*, 80 F.2d 604 (5th Cir. 1935). *95 Barrels* was followed in numerous cases after the enactment of the 1938 Act. *See, e.g.*, *V.E. Irons, Inc. v. United States*, 244 F.2d 34 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957); *United States v. One Device*, 160 F.2d 194 (10th Cir. 1947). The holding also was reflected in FTC decisions. *See, e.g.*, *Sebrone Co. v. FTC*, 135 F.2d 676 (7th Cir. 1943); *Bockenstette v. FTC*, 134 F.2d 369 (7th Cir. 1943). This doctrine is specifically incorporated in 21 U.S.C. § 321(n) (1970), which provides:

[I]n determining whether the labeling is misleading there shall be taken into account . . . not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material with respect to consequences which may result from the use of the article to which the labeling relates . . . .

32. *United States v. Vitamin Indus., Inc.*, 130 F. Supp. 755, 767 (D. Neb. 1955). *See also* *Hall v. United States*, 267 F.2d 795 (5th Cir. 1920) (in determining whether a drug product or an article is misbranded, the language used on the label or package is to be given the meaning ordinarily conveyed by it to those to whom it is addressed).

33. *Royal Baking Powder Co. v. Emerson*, 270 F.2d 429 (8th Cir. 1920), *appeal dismissed*, 260 U.S. 752 (1922); *United States v. Vitamin Indus., Inc.*, 130 F. Supp. 755 (D. Neb. 1955).

34. *United States v. Vitamin Indus., Inc.*, 130 F. Supp. 755 (D. Neb. 1955); *see* *Royal Baking Powder Co. v. Emerson*, 270 F.2d 429 (8th Cir. 1920), *appeal dismissed*, 260 U.S. 752 (1922) (the average buyer is the person of average intelligence, exercising ordinary care in ascertaining what he is purchasing).

What is pertinent is the effect the claims would have on . . . prospective purchasers and actual customers . . . who cannot be presumed to have special expertness or to be unduly cautious, but who are . . . pathetically eager to find some simple cure-all for the diseases with which they are afflicted or who are susceptible to luridly painted scare literature as to the prospect of being disease-ridden unless they consistently partake of the vaunted drug product.

*V.E. Irons, Inc. v. United States*, 244 F.2d 34, 39-40 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957). *Accord*, *United States v. 47 Bottles, More or Less*, 320 F.2d 564, 571 (3d Cir.), *cert. denied*, 375 U.S. 953 (1963).

of the statements to observers of notably superior intelligence,<sup>35</sup> experts in nutrition,<sup>36</sup> overly skeptical buyers,<sup>37</sup> or, at the other extreme, to the mentally dull or infirm.<sup>38</sup> The ultimate impression on the consumer is based not only on what is said but also on all that is reasonably implied.<sup>39</sup> Thus the Commissioner concluded:

When consumers read a label . . . wherein a literally true statement is made, e.g., "Night blindness is caused by a lack of vitamin A," they frequently conclude that the symptom will appear in them unless they use the product being promoted, or . . . even though they may not suffer from the specific symptoms described, the product will be generally good for improving their vision.<sup>40</sup>

The danger of these misleading claims to the health of the consuming public is that the claims tend to encourage people to experiment and delay seeking proper medical attention and treatment.<sup>41</sup>

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35. *United States v. 47 Bottles, More or Less*, 320 F.2d 564 (3d Cir.), *cert. denied*, 375 U.S. 953 (1963); *V.E. Irons, Inc. v. United States*, 244 F.2d 34 (1st Cir.), *cert. denied*, 354 U.S. 923 (1957).

36. *See* cases cited note 35 *supra*.

37. *Id.*

38. *United States v. Vitamin Indus., Inc.*, 130 F. Supp. 755 (D. Neb. 1955). "The purpose of the [Act] is to protect the public . . . which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze." *United States v. 62 Packages*, 48 F. Supp. 878, 887 (W.D. Wis. 1943). *See also United States v. Article . . . Consisting of 216 Cartoned Bottles*, 409 F.2d 734 (2d Cir. 1969); *Gulf Oil Corp. v. FTC*, 150 F.2d 106 (5th Cir. 1945).

39. *See, e.g., United States v. 46 Cartons*, 113 F. Supp. 336 (D.N.J. 1953) (it is not likely that the buying public ordinarily would carefully study or weigh each word); *cf. Aronberg v. FTC*, 132 F.2d 165 (7th Cir. 1942).

40. 38 Fed. Reg. 2147 (1973). The Commissioner also concluded that therapeutic value may not be disclaimed in product labeling, since such statements are also misleading and fail to correct an otherwise false or misleading statement or implication. *Id.* at 20716, *citing United States v. 47 Bottles, More or Less*, 320 F.2d 564 (3d Cir.), *cert. denied*, 375 U.S. 953 (1963); *United States v. Millpax, Inc.*, 313 F.2d 152 (7th Cir.), *cert. denied*, 373 U.S. 903 (1963); *United States v. Nutrition Serv., Inc.*, 227 F. Supp. 375 (W.D. Pa. 1964), *aff'd*, 347 F.2d 233 (3d Cir. 1965); *United States v. Three Cartons*, 132 F. Supp. 569 (S.D. Cal. 1952).

41. *United States v. Kordel*, 164 F.2d 913 (7th Cir. 1947), *aff'd*, 335 U.S. 345 (1948); *United States v. Nutrition Serv., Inc.*, 227 F. Supp. 375 (W.D. Pa. 1964), *aff'd*, 347 F.2d 233 (3d Cir. 1965); *see, e.g., Drown v. United States*, 198 F.2d 999 (9th Cir. 1952) (chiropractor's therapeutic instruments of own design claiming "fantastic" curative qualities on label were dangerous to human health even though harmless, when users, misled by claims, relied upon device instead of medical advice). *See also United States v. 2000 Plastic Tubular Cases*, 231 F. Supp. 236 (M.D. Pa. 1964) (reliance on labeling claims that



It is apparent from the legislative history of the 1938 Act that Congress intended to strengthen governmental protection of the consumer against these false and misleading claims.<sup>42</sup> Moreover, the Food and Drug Administration deals with the public interest and has broad rule-making power to carry out the purposes of the Act.<sup>43</sup> In view of the purposes of the Act and the theory of liberal construction laid down by the courts in this area,<sup>44</sup> the standards set forth in *Storer Broadcasting Co.*<sup>45</sup> to uphold an FCC regulation can be applied to authorize the FDA's promulgation of section 1.17(h)(9)(i).

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toothbrush prevents gum disease, pyorrhea and trench mouth, constitutes a hazard to health because such reliance could prevent or delay effective treatment and lead to serious injury). The court in *2000 Plastic Tubular Cases* did not consider the claims that the toothbrush was effective for prevention of cancer, heart disease, defective birth of offspring, and loss of teeth, because "[f]or the Government to prevail, it is not necessary that all the representations . . . are false; if any single claim in the labeling is . . . misleading, the [article] is misbranded." *Id.* at 240. *Accord*, *United States v. Vitasafe Formula M*, 226 F. Supp. 266, 278 (D.N.J. 1964).

42. See H.R. REP. No. 2139, 75th Cong., 3d Sess. 1 (1938):

This act seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the [Act] of June 30, 1906 . . . .

While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions.

*Id.*

43. See Austern, *Sanctions in Silhouette: An Inquiry Into the Enforcement of the Federal Food, Drug, and Cosmetic Act*, 51 CALIF. L. REV. 38, 39 (1963). The courts have given broad scope to the discretion and informed judgment of the administrative agency. "That judgment, if based on substantial evidence of record, and if within statutory and constitutional limitations, is controlling even though the reviewing court might on the same record have arrived at a different conclusion." *Federal Security Adm'r v. Quaker Oats Co.*, 318 U.S. 228 (1943). "The wisdom of the principle adopted is none of [the Court's] concern . . . . Our duty is at an end when . . . the . . . action is based upon substantial evidence and is consistent with the authority granted by Congress." *SEC v. Chenery Corp.*, 332 U.S. 194, 207 (1947).

44. Public interest demands that the Act, being remedial in nature, should be construed liberally to meet its intended beneficial purposes. See, e.g., *United States v. An Article of Drug*, 394 U.S. 784 (1969); *United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. "Cal's Tupelo Blossom U.S. Fancy Pure Honey"*, 344 F.2d 288 (6th Cir. 1965); *United States v. Lee*, 131 F.2d 464 (7th Cir. 1942). This remains true despite the penal nature of the Act. See also *United States v. Kordel*, 164 F.2d 913 (7th Cir. 1947), *aff'd*, 335 U.S. 345 (1948); *United States v. Omar, Inc.*, 91 F. Supp. 121 (D. Neb. 1950) (public and social purposes served by such legislation greatly exceed the inconvenience and hardship imposed on the individual).

45. 351 U.S. 192 (1956). See also note 25 *supra*.

## II. THE MISBRANDING PROVISION: SANCTIONS AND IMPLICATIONS

Nutrition labeling regulations have the force and effect of law.<sup>46</sup> The Supreme Court in *Abbott Laboratories v. Gardner*<sup>47</sup> stated that if the regulations are "within the Commissioner's authority, they have the status of law and violations of them carry heavy criminal and civil sanctions."<sup>48</sup> Violation of this prohibition against making claims of therapeutic value is a violation of the misbranding provision of the Act<sup>49</sup> and subject to its triple sanction of seizure,<sup>50</sup> injunction<sup>51</sup> and criminal prosecution.<sup>52</sup> While criminal prosecutions for charges of economic deception have been relatively infrequent, the threat of criminal prosecution by the agency's "lifted eyebrow" technique<sup>53</sup> has been effective in deterring violations of the Act.<sup>54</sup>

The purpose of the seizure provision is to "arrest the distribution of an article . . . whose labeling is fraudulent or misleading, *pending*

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46. *See Toilet Goods Ass'n v. Gardner*, 387 U.S. 158 (1967); *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967) (rule promulgated under § 701(a) of the Act has force of law and may be judicially reviewed at outset). *But see Cody, Authoritative Effect of FDA Regulations*, 24 FOOD DRUG COSM. L.J. 195 (1969) (arguing that § 701(a) authorized only interpretive, not legislative, rules); Thompson, *FDA—They Mean Well, But . . .*, 28 FOOD DRUG COSM. L.J. 205 (1973).

47. 387 U.S. 136 (1967).

48. *Id.* at 151-52.

49. *See* note 9 *supra*.

50. 21 U.S.C. § 334(a) (1970) (permits multiple seizure of misbranded articles); *see, e.g., United States v. Vitasafe Corp.*, 345 F.2d 864 (3d Cir. 1965); *United States v. Detroit Vital Foods, Inc.*, 330 F.2d 78 (6th Cir. 1964); *United States v. Four Devices*, 176 F.2d 652 (10th Cir. 1949).

51. 21 U.S.C. § 332(a) (1970); *see, e.g., Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, *rehearing denied*, 340 U.S. 857 (1950); *United States v. Vitasafe Corp.*, 345 F.2d 864 (3d Cir. 1965); *United States v. Ellis Research Laboratories, Inc.*, 300 F.2d 550 (7th Cir. 1962); *United States v. Nutrition Serv., Inc.*, 227 F. Supp. 375 (W.D. Pa. 1964), *aff'd*, 347 F.2d 233 (3d Cir. 1965).

52. 21 U.S.C. § 333 (1970). Section 333(a) provides that violation carries a possible sanction of imprisonment for not more than one year, or \$1,000 fine, or both, and section 333(b) imposes more severe penalties in cases of violation of any provision of section 331 with intent to defraud or mislead. *See, e.g., United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Millpax, Inc.*, 313 F.2d 152 (7th Cir.), *cert. denied*, 373 U.S. 903 (1963); *United States v. Kordel*, 164 F.2d 913 (7th Cir. 1947), *aff'd*, 325 U.S. 345 (1948).

53. "Regulation by lifted eyebrow" is an informal method of enforcement by the suggestion or implied threat of action or publicity. This procedure is not unique to the FDA. *See* 1 DAVIS, ADMINISTRATIVE LAW TREATISE § 4.03, at 241-42 (3d ed. 1958); Austern, *supra* note 43, at 41.

54. *See Developments in the Law, supra* note 6, at 693-94.

a determination of the issue of . . . misbranding."<sup>55</sup> Under section 1.17(h)(9)(i), however, there is no need to make a subsequent misbranding determination.<sup>56</sup> The regulation declares that claims of therapeutic value are inherently misleading; hence, products containing such labeling claims are misbranded and in violation of the Act. Therefore, the purpose of the seizure provision is limited to removing *misbranded* products from distribution. As a result, there may be an increase in the use of the criminal sanction as a supplement to seizure and injunction. This criminal prosecution sanction, requiring no element of criminal intent to defraud, has been severely criticized.<sup>57</sup>

The prohibition of statements of therapeutic value eliminates the need for the Government to classify foods as drugs before making the determination of misbranding. The tendency in the past has been for the courts to make a two-step determination in imposing liability:<sup>58</sup> first, that the claims bring the article within the definition of a drug,<sup>59</sup>

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55. *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 601, *rehearing denied*, 340 U.S. 857 (1950) (emphasis added).

56. See note 61 *infra*.

57. See generally Austern, *supra* note 43. Austern forcefully argues against strict criminal liability:

Criminal prosecution can follow with equal ease for violations of minor economic regulations as for major threatened injury to the public health. The same penal consequences can flow from using the wrong words . . . as would follow from the addition of a poison to that food. . . .

This indiscriminate application of the same drastic criminal sanction, irrespective of the character or magnitude of the violation involved, and under the absolute rule of strict criminal liability, is a historical accident in this field.

*Id.* at 46. But see *United States v. Dotterweich*, 320 U.S. 277, 281 (1943) (effective protection of the public demands imposing the risk of liability on those responsible for violations irrespective of their knowledge). See also *Developments in the Law*, *supra* note 6, at 693-701.

58. See generally Erlebacker, *When Is a "Cosmetic" Also a "Drug" Under the Federal Food, Drug and Cosmetic Act*, 27 *FOOD DRUG COSM. L.J.* 740 (1972).

59. See *United States v. Article . . . Consisting of 216 Cartoned Bottles*, 409 F.2d 734 (2d Cir. 1969) (facial lotion classified as drug); *United States v. "Cal's Tulepo Blossom U.S. Fancy Pure Honey"*, 344 F.2d 288 (6th Cir. 1965) (honey classified as drug); *Bradley v. United States*, 264 F.2d 79 (5th Cir. 1920) (mineral water classified as drug); *United States v. Articles of Drug*, 263 F. Supp. 212 (D. Neb. 1967) (vitamin laxative classified as drug); *United States v. Nutrition Serv., Inc.*, 227 F. Supp. 375 (W.D. Pa. 1964), *aff'd*, 347 F.2d 233 (3d Cir. 1965) (dietary aid classified as drug); *United States v. 46 Cartons*, 113 F. Supp. 336 (D.N.J. 1953) (cigarette with labeling claiming to mitigate respiratory and other ailments classified as drug). Section 321(g)(1)(b) of the Act defines

and secondly, that since these claims appear on the label, they constitute misbranding because they are false and misleading.<sup>60</sup> Under the new regulation, the Government need not prove that the food is a drug, for the prohibition applies directly to food products and supplements. The Government is required to prove only that a claim of therapeutic value appeared in the labeling.<sup>61</sup>

While consumer protection is furthered by the prohibition of therapeutic claims and implications in labeling, the public is still subject to these same statements in advertising because the FDA does not have the authority to regulate advertising of food products.<sup>62</sup> The Federal Trade Commission (FTC), however, is granted special authority over all advertising of foods, drugs, devices and cosmetics.<sup>63</sup>

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a "drug" as "articles *intended* for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." 21 U.S.C. § 321(g)(1)(b) (1970) (emphasis added). It is the *intended* use of the article that determines whether it is a drug, regardless of its inherent properties or dictionary definition. *United States v. Articles of Drug*, 263 F. Supp. 212, 215 (D. Neb. 1967). The intended use is determined by claims on the labels, accompanying labeling, promotional material, advertising or any other relevant sources. *United States v. Article . . . Consisting of 216 Cartoned Bottles*, 409 F.2d 734, 742 (2d Cir. 1969); *United States v. Articles of Drug*, 263 F. Supp. 212, 215 (D. Neb. 1967). Thus, if a food or food supplement makes any claims of therapeutic value, it may also be classified as a drug for the purposes of the law. The two terms are not mutually exclusive. *See* 38 Fed. Reg. 20710 (1973). *See also* S. REP. NO. 361, 74th Cong., 1st Sess. 3-4 (1935):

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.

*Id.*

Therefore attempts by producers of food products or supplements to avoid the effect of the regulation by claiming that the product is a drug, not a food, may be ineffective.

60. *See* cases cited note 59 *supra*.

61. Nevertheless, the courts will have to determine whether the statement was, in fact, a claim or implication of therapeutic value.

62. This is specifically acknowledged by the Commissioner. *See* 38 Fed. Reg. 6951 (1973). Following intensive legislative battles to decide whether the FDA should have jurisdiction over false and misleading advertising, all sections pertinent to advertising in proposed bills were incorporated into the FTC Wheeler-Lea Bill, 15 U.S.C. § 44 *et seq.* (1970). *See also* S. 5, 75th Cong., 1st Sess. (1937); 81 CONG. REC. 2018-19 (1937).

63. 15 U.S.C. §§ 52-56 (1970).

In *National Petroleum Refiners Association v. FTC*<sup>64</sup> the Court of Appeals for the District of Columbia recently held that the FTC, under the Federal Trade Commission Act, is empowered to promulgate substantive rules of business conduct—Trade Regulation Rules. The court stated that the FTC, under its mandate to prevent “unfair or deceptive acts or practices,” has the responsibility and expansive power to protect the consumer from being misled by governing the conditions under which goods are advertised, and to proscribe conduct it deems harmful to the consumer.<sup>65</sup> Indeed, in light of the FTC’s broad power and the courts’ favorable attitude toward substantive rule-making, it would seem appropriate for the FTC to promulgate a regulation similar to section 1.17 that prohibits misleading statements of therapeutic value from appearing in advertising, thereby fully protecting the consumer from these claims.

A major objection to the regulation<sup>66</sup> is that the prohibitions re-

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64. 482 F.2d 672 (D.C. Cir. 1973) (upheld, as within the rule-making power of the FTC, a trade regulation rule declaring that failure to post octane numbers on gasoline pumps at service stations would be an “unfair method of competition” and a “deceptive practice” in violation of the Federal Trade Commission Act). In upholding the power of the FTC to promulgate substantive rules, the court stated:

[J]udicial precedents concerning rule-making by other agencies and the background and purpose of the Federal Trade Commission Act lead us liberally to construe the term “rules and regulations.” The substantive rule here unquestionably implements the statutory plan.

*Id.* at 678.

65. *Id.* at 685.

66. The National Health Federation voiced strong objection to the regulation, alleging that the FDA is trying to crack down on health food stores by forcing food supplements that do not meet the requirements of the regulation off the market. The Federation reacted to the regulation by giving strong support to the Hosmer Bill, H.R. 643, 93d Cong., 1st Sess. (1973), which would limit the authority of the FDA in regulating food supplements. Responding to inquiries concerning the potential effect of these regulations on vitamin-mineral products in the marketplace, the Assistant General Counsel of Health Education and Welfare (Food and Drug Division) stated:

The only vitamin-mineral products now on the market that will be “forced off” because of the FDA regulations are those that have inherently irrational formulations or rest solely upon unsupported claims. The vast majority of the vitamin-mineral products affected by the new regulations will require only reformulation and relabeling. We cannot believe that any manufacturer will be unable to continue in business. Such statements are emotional reactions, perhaps due to some of the erroneous statements that have been made about the new regulations, and do not reflect an accurate understanding of the regulations.

Letter from Peter Hutt to Senators Nelson, McGovern and Cranston, and Congressmen Harrington and Eckhardt, July 9, 1973, on file with the *Urban Law Annual*.

move from the consumer's view statements that may be literally true, yet which the Commissioner has determined to be inherently misleading, in spite of today's emphasis on providing the consumer with as much labeling information as possible. The FDA, however, faces the difficult task of balancing two consumer interests. The first is the need to protect consumers who are either incapable themselves of making a rational choice based on these claims or who may be easily misled because of the need for some cure-all, especially the elderly and the infirm. The second interest is that of the consumer who is objective enough to see through any potentially misleading statement and who demands to know all the relevant facts. In balancing these interests, the FDA must consider the basic purpose of the Act—to protect the average consumer who, because of sophisticated promotional techniques and modern industrialism, is unable to protect himself. In view of the dominant remedial purposes of the Act and the broad statutory authority to promulgate rules to implement these purposes, the Commissioner was authorized and justified in promulgating section 1.17(h)(9)(i) of the nutrition labeling regulation. Therapeutic information and advice should come from the consumer's doctor rather than from mass promotional techniques.

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