REGULATING THE LABELING OF OVER-THE-COUNTER DRUG PRODUCTS

*Isidore Michael Schulman**

People in the United States today use over-the-counter [hereinafter OTC] drugs far more often than prescription drugs to treat their illnesses. Self-medication is relatively inexpensive and is more readily available than professional help. In 1977 the American Pharmaceutical Association estimated that in excess of five billion dollars worth of OTC drug products were sold to consumers to treat over seventy percent of all illnesses.[1] Today, the use of OTC drugs continues to grow in importance as both the costs of medical care and the demands on physicians' time increase. This use of OTC drugs entails risks and may be detrimental to the public's health—especially when these drugs are misused.

By definition, consumers can use OTC drug products without consulting a physician. Presumably, these drugs do not present as significant hazards to users as do prescription drug products. However, OTC drug products may still be dangerous. The available research in this area indicates that the misuse of OTC drugs or misdiagnosis of medical problems by consumers has caused serious medical complications including chronic poisoning, physiological changes, and sometimes even addiction.[2] While this has been partly caused by the negligence or recklessness of consumers and their inherent inability to self-diagnose every illness, it can also be attributed to poorly designed or worded labels.

This article explores the need for a definitive labeling program and describes an approach which will satisfy that need. The present system of OTC drug labeling is examined in Part I in light of the special role the drug label plays in informing consumers of the purposes and uses of an OTC drug product. Part II discusses the need for establishing a uniform approach to OTC drug labeling, including adoption of a required standardized format with limited use of presently approved ter-

*Former Adjunct Assistant Professor of Law, University of Southern California Law Center; Consultant to the Food and Drug Administration on Miscellaneous Internal Over-the-Counter Drug Products (1975-1981). A.B., University of California at Berkeley, 1974; J.D., University of Santa Clara, 1976.

I wish to acknowledge the able research assistance of Gary Steven Schwend, a second-year law student at the USC Law Center. Michael J. Collard, *Journal of Legislation* staff member, served as Notre Dame research assistant for this article.

1. THE AMERICAN PHARMACEUTICAL ASSOCIATION, HANDBOOK OF PRESCRIPTION DRUGS at xi (5th ed. 1977).
2. It is difficult to trace clear figures as to the extent of these risks. However, for one good source, see *Home Medication and the Public Welfare*, 136 ANN. N.Y. ACAD. SCI. 102 (1965).

minology. Finally, in Part III, various examples of deceptive labeling are provided along with recommendations as to how they should be regulated under a standardized approach.

PRESENT LABELING REGULATION

A label plays a unique role in communicating information to consumers. Consumers use labels to tell themselves whether the drugs suit their needs and how the drugs are to be used. They will usually read the label both in the store prior to purchase and in the home after purchase. Consequently, manufacturers use drug product labels, like advertisements, to communicate information in a style and format that encourages product selection and, unlike advertisements, to communicate precise and detailed use information. Use information facilitates self-diagnosis. Thus, use information is particularly important when the product is an OTC drug because an improper self-diagnosis could cause serious harm to the consumer.

In an effort to lessen the harm caused by improper self-diagnosis, the government could transfer all OTC drugs to prescription status. This alternative is impractical because the price of obtaining these products would rise, adding costs to an already expensive health-care system. Many people who need the help of OTC drugs would go untreated because they could not afford to get a prescription from a doctor. A better alternative, and the one our government is trying to follow, is to remove all unsafe and ineffective products from the marketplace and to require *adequate* labels for those products that remain on the OTC market. Therefore, it makes little sense for the government to go through the long process of reviewing all OTC drug products for safety and effectiveness and then to allow the manufacturers to promote approved products as they see fit. Insuring proper labeling is a crucial element, since misuse of OTC drugs can cause as much or more harm than ineffective or unsafe drugs.

The Food and Drug Administration [FDA] has been regulating OTC drugs for over sixty years.[3] Until 1962, its primary regulatory approach had been to remove unsafe or misbranded OTC drug products from the market by means of individual court action or reclassification of these drugs to prescription status.[4] The assumption underlying this approach was that most OTC drug products were safe and could be marketed without FDA clearance.

After the passage of the Federal Food, Drug and Cosmetic Act [FDCA][5] in 1962, however, the FDA approach to regulating OTC

3. Food and Drug Act of 1906, 34 Stat. 768 (1906). For a history of the earliest food and drug laws, see Janssen, *America's First Food and Drug Laws*, 30 FOOD, DRUG & COSM. L.J. 665 (1975).

4. *See* Lee, *The Enforcement Provisions of the Food, Drug, and Cosmetic Act*, 6 LAW & CONTEMP. PROBS. 70, 70-71 (1939).

5. 21 U.S.C. §§ 301-392 (1976).

drugs changed considerably.[6] By that Act, Congress gave the FDA the power to require a showing that all OTC drugs, prior to being marketed, were safe and effective. Congress indicated to the FDA that, among other things, the safety and effectiveness of OTC drug products depends upon the availability of adequate and objective public information about the products. Without such information on the label, OTC drug products were to be considered misbranded, and the FDA was directed to remove them from the market.[7]

To implement this policy the FDA initiated the OTC Drug Review Panels [hereinafter Panels].[8] These panels of experts reviewed data on the active ingredients in OTC drug products and made recommendations to the FDA. The recommendations described the conditions under which a drug could be considered safe, effective, and properly labeled for OTC use.[9] The recommendations were published as reports, and the public has been given an opportunity to comment on them.[10] The FDA has the final power of approval of the recommendations.[11] The legality of this review process has been affirmed by the Supreme Court[12] and reapproved by the Congress.[13] At present the panel review process is complete but the FDA has taken final action on only a small percentage of the reviewed drug products.[14]

Although the FDA issued internal regulations which detailed the procedures the Panels should follow, it did not provide the Panels with much guidance as to what constitutes proper labeling.[15] As a result of this deficiency the labeling recommendations in the completed Panel reports have varied widely. Consequently, as the FDA completes its final review of the Panel reports, the lack of sufficient standards by which to judge the adequacy of labeling has caused confusion and inconsistent treatment of the many categories of drugs. The following comments are an attempt to provide a framework for, and to add clarity to, the FDA OTC drug labeling policy.

STANDARDIZING LABELING

Current FDA internal regulations governing OTC drug labeling do not adequately define the criteria to be used in reviewing OTC drug

6. *See* Harlow, *The FDA's OTC Drug Review: The Development and an Analysis of Some Aspects of the Procedure*, 32 FOOD, DRUG & COSM. L.J. 248, 250 (1977).
7. 21 U.S.C. §§ 352(b), 331(b), 334(a)(1) (1976).
8. 21 C.F.R. § 330.10 (1981); 37 Fed. Reg. 85 (1972).
9. *See* Harlow, *The FDA's OTC Drug Review: The Development and an Analysis of Some Aspects of the Procedure*, 32 FOOD, DRUG & COSM. L.J. 248 (1977); 21 C.F.R. § 330.10 (1981).
10. 21 C.F.R. § 330.10 (1981).
11. *Id.*
12. Weinberger v. Bentex Pharmaceuticals, 412 U.S. 645, 653 (1972).
13. Drug Listing Act of 1972, *codified at* 21 U.S.C. §§ 331, 355, 360 (1976).
14. As of January 1, 1982, only four OTC drug categories, representing two percent of all OTC drugs to be reviewed, have been completed. 21 C.F.R. §§ 331 (antacids), 332 (antiflatulents), 310.525 (sweet spirits of nitre), 310.519 (daytime sedatives) (1981).
15. 21 C.F.R. § 201.6 (1981).

product labels. The Panels are to consider a drug misbranded if the following requirement is not satisfied:

> Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.[16]

The lack of specificity and definition in the wording of this regulation makes it more appropriate for a case-by-case review scheme than its intended purpose as a guideline for across-the-board rulemaking. Although some flexibility is necessary to accommodate specific cases, the FDA should develop specific and well-defined criteria to be applied consistently to all drug categories when determining whether the label is adequate.

The first criterion which must be applied to any language appearing on an OTC label is medical accuracy. The label is usually the major, and often the only, source of information available to the consumer about the proper use of a drug. Even when other sources are available, consumers may rely solely on the information contained on the label because of its convenience. Because of the reliance which consumers place on the information appearing on an OTC drug product label, the product cannot be considered safe and effective if that information is inaccurate in any respect.[17] Medical accuracy includes not only the truthfulness of the information appearing on the label, but also the completeness of that information. Thus, under the FDCA, the manufacturer is required to truthfully disclose all information necessary for the safe and effective use of any OTC drug product.[18]

A standard of comprehensibility should also be applied to OTC drug labeling language. Clear and simple language should be used in labeling in order to maximize consumer understanding. A medically accurate but incomprehensible label cannot promote safe and effective self-medication.

The FDA has required that labeling information be constructed "to be read and understood by the ordinary individual, including individuals of low comprehension."[19] This requirement cannot be met without infusing linguistic and communicative expertise into the selection process for every drug category. Already the Panels have made numerous labeling recommendations that contain incomprehensible language.[20] Although technical language may be the most medically accurate ex-

16. 21 C.F.R. § 330.10(a)(4)(v) (1981).
17. United States v. Rutherford, 442 U.S. 544 (1979).
18. 21 U.S.C. § 355(b) (1976).
19. 21 C.F.R. § 330.10(a)(4)(v) (1981).
20. For example:
Statement of Identity and Indications—"Ophthalmic hypertonicity agent." "for the

pression of some information, when it is required it should be accompanied by interpretive language of common usage. Clearly, the FDA has not perceived the importance of comprehensibility, because it continues to insist that language experts are not necessary for proper labeling.[21]

Limitation of Terminology

In order to help achieve a consistent system of labeling regulation, the FDA has developed a policy of terminology limitation. In the Tentative Final Order for Antacid Products, issued on November 12, 1973, the FDA first enunciated the policy that manufacturers may only use specifically approved terminology for warnings, directions for use, and indications on labels.[22] This order responded to numerous comments that "similar intent" language should be allowed.[23] The order stated that "[t]he use of dissimilar labeling in situations involving identical uses and hazards would cause consumer confusion and could lead to deception and unsafe use."[24] The FDA therefore concluded that the labeling specified in the monograph[25] would be mandatory.[26]

Comments submitted in response to the Tentative Final Order for Antacid Products again requested that the FDA allow similar intent language. In the Final Order, issued on June 4, 1974, the FDA supported its position taken in the Tentative Final Order:

> The Commissioner believes that uniformity in labeling language is essential to consumers. For this reason, the combining of warnings is permitted only where it will retain uniform terminology. Allowing minor word variations, or rearrangement of the same words, would result in dissimilar or confusing warnings which would not be in the best interests of the public.[27]

Confusion over this issue persisted despite these seemingly unambiguous statements in the Tentative Final Order and the Final Order for the antacid monograph. Part of the confusion arose from the language of the Final Order, which required that "[t]he labeling of the product *represents or suggests* the product as an antacid to relieve the following symptoms: 'heartburn,' 'sour stomach,' and/or 'acid indigestion.' " (Emphasis added.)[28] The FDA acknowledged the possibility of

---

temporary relief of corneal edema." Ophthalmic products proposed monograph, subpart D, § 349.70(a) and (b), 45 Fed. Reg. 30,002, 30,049 (1980).

Warnings—"Use of solution with occlusive bandages not advisable." Antimicrobial I products proposed monograph, subpart D, § 33.90(b)(2), 39 Fed. Reg. 33,102, 33,141 (1974).

21. 37 Fed. Reg. 9468 (1972).
22. 38 Fed. Reg. 31,260 (1973).
23. *See* note 10 *supra* and accompanying text.
24. 38 Fed. Reg. 31,260, 31,261 (1973).
25. 38 Fed. Reg. 8714 (1973).
26. 38 Fed. Reg. 31,260, 31,261 (1973).
27. 39 Fed. Reg. 19,862, 19,868 (1974).
28. *Id.* at 19,876.

confusion over this language and issued an amendment which altered the language to read: "The labeling of the product *shall identify* the product as an 'antacid' to alleviate the following symptoms: 'heartburn,' 'sour stomach,' and/or 'acid indigestion.' "(Emphasis added.)[29] The amendment notice included the Commissioner's statement that "the terms recommended by the Panel fully meet the intent of the regulation that allowing each manufacturer to select the words to be used would result in continued consumer confusion and deception, and therefore that the evidence presented does not justify expansion of the present number of permitted terms."[30]

Although the FDA's official policy on exclusivity has not wavered, resistance to it continues. The drug industry maintains that this policy is unnecessary to achieve truthful and non-deceptive OTC drug labeling.[31] Certain Panels and Panel members have voiced support for the industry's position. The Panel on antiperspirants went so far as to issue a minority opinion in its proposed monograph indicating the belief of two of its members that "to enumerate allowable words and phrases and to disallow all others is unduly restrictive and subject to inherent difficulty in enforcement."[32] In its proposed monograph, the Panel for ophthalmic drug products indicated limited support for this position:

> The Panel entirely supports the FDA in its determination to review, monitor, and give approval to truthful and non-deceptive labeling to provide consumer protection.
>
> On the other hand, the Panel believes that industry should have the opportunity to use unadorned synonyms to acceptable terminology as long as it is truthful, non-deceptive, and given prior approval by FDA.[33]

The FDA's decision to require manufacturers to use only the terminology established in the monographs is dictated by the need to protect consumers from unsafe or ineffective products. Safety and efficacy determinations for OTC drug products cannot be made in the abstract. The precise use for which the product is marketed is an integral part of those determinations. Once the FDA has determined that a particular product is safe and effective for a particular use, allowing the manufacturer to describe the product by alternative or unapproved language could result in the marketing of the product for a use for which the FDA had not found the product safe and effective.

By limiting the terminology with which manufacturers are allowed to describe their OTC drug products to certain approved terms, the FDA performs three vital services to consumers. First, restriction to limited terminology reduces the deceptive practice of false differentia-

29. 40 Fed. Reg. 11,718, 11,719 (1974).
30. *Id.* at 11,718.
31. FEDERAL TRADE COMMISSION, ADVERTISING FOR OVER-THE-COUNTER DRUG ADVERTISING: STAFF REPORT 151-84 (1979) (Pub. Rec. No. 215-51).
32. 43 Fed. Reg. 46,694, 46,724-25 (1978).
33. 45 Fed. Reg. 30,002, 30,023 (1980).

tion—use of truthful claims to mislead and falsely influence the purchase choice of consumers.[34] Second, comparison shopping for OTC drugs is enhanced when descriptive terms are limited. Finally, the use of limited terminology in drug labeling has an educational effect on consumers because it encourages the establishment of a standardized vocabulary of selected medical terminology. This vocabulary assists consumers in future self-medication efforts.

The drug industry maintains that the substitution of synonyms for approved terms will not change a truthful labeling claim into a deceptive one.[35] This argument rests on several dubious assumptions. First, it assumes that proper synonyms of approved terminology exist. According to linguistic experts, the occurrence of identical or perfect synonyms is extremely rare.[36] Somewhat more prevalent are functional synonyms, which are equivalents as to all important components of meaning and in all relevant contexts.[37] However, most synonyms are of a third type. These common synonyms share some but not all important components of meaning.[38] These various types and degrees of snyonymity suggest problems with judging the acceptability of specific synonyms.

The industry position is also based on the assumption that a truthful claim cannot be a deceptive claim. The confusion that can result from use of truthful claims to falsely differentiate identical products was made apparent in the labeling of internal analgesic drugs. Internal analgesics have been found safe and effective "for the temporary relief of occasional minor aches, pains and headache."[39] Although the Panel reviewing analgesics also noted that internal analgesics give temporary relief from "muscle aches," "stiffness," "pain of toothaches," "teething," "dental procedures and dental work," "muscle soreness," "pain due to headcolds," "nervous headache," "tension headache," and "simple pain of innoculations and immunizations,"[40] it decided not to allow manufacturers to make these claims on product labels. It believed that consumers would be confused and misled if products having identical formulations and offering identical therapeutic effects were marketed for a wide variety of claimed uses.[41] A consumer could mistakenly conclude that one product is only safe and effective for "simple headache," another for "tension headache" and a third for "body aches," and, as a result, purchase all three when any one product would be safe and effective for the three claimed uses. It is apparent that allowing

34. Problems with this practice will be more fully discussed in Part III, *infra*.
35. FEDERAL TRADE COMMISSION, ADVERTISING FOR OVER-THE-COUNTER DRUG ADVERTISING: STAFF REPORT 151-84 (1979) (Pub. Rec. No. 215-51).
36. *Id.*
37. *Id.*
38. *Id.*
39. 42 Fed. Reg. 35,346, 35,355 (1977).
40. *Id.*
41. *Id.*

manufacturers to make any truthful claim would not always result in truthful and non-deceptive labeling.

Another argument advanced by the drug industry in favor of unrestricted use of unapproved truthful synonyms is that receiving FDA approval for this terminology is either impossible or impractical.[42] This argument is belied by the fact that industry participation in the term-selection process in each of the Panels was highly encouraged. The Panels were exhaustive in their review of labeling claims; all claims that were submitted were reviewed. The FDA terminology limitation policy gave industry an incentive to submit to the FDA all terms that they might wish to use. To allow the use of unapproved synonymous terminology would have encouraged manufacturers to withhold alternative terminology in order to avoid FDA rejection of that terminology. Manufacturers desiring to use unsubmitted synonyms are not left without recourse. Even when the word-selection process is completed and the final monograph has gone into effect, a manufacturer may still petition the Commissioner of Food and Drugs to amend the monograph and allow the use of a particular truthful and non-deceptive claim.[43]

Label Format

Use information must be communicated to consumers if it is to serve its purpose. In addition to content, the design of the label in its entirety and the placement of information upon it must be examined. The FDA has been given the authority under the FDCA to regulate OTC drug label formats;[44] specifically, the conspicuousness of the information on the label.[45]

In accordance with the FDCA, the FDA has adopted a series of regulations which require that information: 1) of a specific type appear on the label,[46] 2) be displayed at specific places on the label,[47] and 3) appear in a prominent manner.[48]

Despite these detailed regulations, the information on labels is not as accessible as it could be. Labeling information, as currently presented, is not necessarily salient because placement can be on the sides or backs of labels (competing brands may differ), with lettering

42. FEDERAL TRADE COMMISSION, ADVERTISING FOR OVER-THE-COUNTER DRUG ADVERTISING: STAFF REPORT 151-84 (1979) (Pub. Rec. No. 215-51).
43. 21 C.F.R. § 330.10(a)(12) (1981).
44. 21 U.S.C. § 352 (1976).
45. 21 U.S.C. § 352(c) (1976):
> If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

46. 21 C.F.R. §§ 201.1, .2, .5 (1981).
47. *Id.* at §§ 201.15(a)(1), .15(a)(2) (1981).
48. *Id.* at §§ 201.15(3)-.15(5) (1981).

that can be difficult to read. Thus, important information may not be likely to catch the consumer's eye in a quick scan of the label. This may mean that much of the information that is useful before purchase may not be read until after purchase.

Problems associated with format can be remedied by requiring better package design. A first step would be to require standard placement of required information. The required information could be put in the same place on all packages, perhaps using some graphic device to make it easily perceptible. A notice on the front of the package directing the consumer's attention to the relevant information on the label could be required. This reminder should be noticeable at a glance of the package. Other regulations could prohibit the use of color schemes that are hard to read and imperceptible print styles. Word order or placement rules could also be employed.

CONTROLLING DECEPTIVE LABELING

The FDA has broad power to regulate deceptive labeling claims. However, the FDA has made little use of this power. Various Panels have suggested in their final reports that the FDA, through the use of its regulatory powers, should restrict the use of various false and misleading terminology.[49] The following section will consider the suggestions of those Panels and delineate four types of deceptive labeling which the FDA should actively seek to prohibit through regulation: 1) true but misleading claims, 2) false claims, 3) claims which promote inappropriate use through truthful representations, and 4) truthful claims which falsely differentiate between similar products.

True But Misleading Representations

Although the specifics of a given claim for a product may be true, the general impression of that claim upon a reader may be a false one. This may be due, in part, to the consumer's reading the label carelessly and not noticing its subtleties. When the class of persons for whom an OTC drug may be safe and effective is broadly defined, manufacturers are induced to persuade persons for whom that drug would not be safe and effective to use it.[50]

One form of ambiguity exists when a term used on a label is capable of varying interpretations. The Anorectal Panel discovered such an ambiguity in the labeling of vasoconstrictor hemorrhoid products. The Panel disallowed the use of the term "shrink" unless preceded by the modifier "temporarily" because the use of "shrink" without such a modifier could refer to either a temporary or a permanent condition. The Panel concluded that the "public is likely to consider that a perma-

49. 42 Fed. Reg. 35,346, 35,434-35 (1977).
50. This technique is only natural due to the manufacturers' incentive to reach the widest possible market.

nent change is to be expected," whereas the available data indicated that only a temporary reduction in swelling was possible.[51]

Similarly, a claim of a "guarantee of relief" is misleading unless the conditions attached to the guarantee are provided. A vague assertion of such a guarantee is not only unhelpful (which may or may not be grounds for finding deception), but also may induce an otherwise undesired purchase.[52]

Labeling may also be vague or ambiguous as to an OTC drug product's "time of onset of relief." One example of this problem is the Cough, Cold, Allergy, Bronchodilator and Antiasthmatic Products [CCABA] Panel's banning of the use of the words "fast" or "prompt" because such claims were indeterminable.[53] Vague claims of this nature are intended to increase product selection rather than affect use and therefore should be treated differently than misleading "indications for use."

One common type of misleading claim is the vague indication for use. As the previous section discussed, the FDA presently prohibits manufacturers from using indication-for-use claims which the FDA has not approved. In this regard, the advisory Panels have suggested the prohibition of indications such as "jumpy nerves," "fretfulness," and "under the weather."[54] For other potentially misleading terms which are frequently used, a definition by the FDA would be helpful.[55]

This definitional approach was employed by the Topical Antimicrobial Panel when it chose to define rather than reject the term "antiseptic." The Panel noted that "[o]ver the years, the exaggerated labeling claims on a large variety of products containing antimicrobials has led to misuse and abuse of the term 'antiseptic.' "[56] To counteract this effect, the Panel decided "to eliminate the confusion by developing a rigorous definition of a Skin Antiseptic," which the Panel concluded is "a safe, nonirritating, antimicrobial-containing preparation which prevents overt skin infections."[57] Although this approach need not require any specific action by the FDA, it should be used when possible. To augment this system, the FDA could require that qualifying statements be inserted in certain obvious cases. For example, any use of the term "guarantee" should require further definition on the product label.

---

51. 45 Fed. Reg. 35,576, 35,626 (1980).
52. *See also* text accompanying note 67 *infra*.
53. 41 Fed. Reg. 38,312, 38,343 (1976).
54. 42 Fed. Reg. 35,346, 35,355 (1977). Other claims rejected by Panels on similar grounds include: "sustained," "prolonged," and "effective over a long period of time"—Anorectal Panel, 45 Fed. Reg. 35,576, 35,602 (1980); "fast," "sudden," "immediate," "prompt" and "poignant"—External Analgesic Panel, 44 Fed. Reg. 69,768, 69,844 (1979); "fast-action"—Ophthalmic Panel, 45 Fed. Reg. 30,002, 30,035 (1980); "fast-acting," "quick," and "prompt"—Skin Bleaching Panel, 43 Fed. Reg. 51,546, 51,554 (1978).
55. The FDA is empowered to establish such definitions by 21 U.S.C. 341 (1976).
56. 39 Fed. Reg. 33,103, 33,114 (1974).
57. *Id.*

The specific action that the FDA should take against misleading labeling claims depends on the form of the misleading terminology. Misleading indications for use should be absolutely prohibited. New drug products should be approved only after their labeling claims are approved. The FDA should also define commonly used terms like "antiseptic" and ban commonly misused terms such as "shrink."

It would be difficult to require proof of claims concerning time of onset of relief, whether that burden is placed on the manufacturer or the FDA. Nevertheless, if a manufacturer voluntarily uses vague terms in this manner, it should be required to show, when asked, that its product justifies the use of such terms. Thus, a manufacturer claiming "fast" relief would have to show (through previously submitted data) just how its product is "fast" compared to similar products.

As to the many other possible misleading claims, the FDA should provide manufacturers with some indication as to what is or is not acceptable. Vague, uninformative terms need not be banned, but those which confuse or are capable of confusing the consumer into purchasing an undesired product should be prohibited. In terms of advertising, the Federal Trade Commission has taken the position that a vague term should be interpreted broadly, thus giving the manufacturer the benefit of the doubt.[58] The FDA should have a similar rule. Finally, a general rule against vagueness should be promulgated, although it should be made clear that not all words which may be vague, but only those capable of misleading a significant portion of the public, would be prohibited.

False Representation

The plain truthfulness of language used on OTC drug labels can usually be factually proven one way or the other. Problems for the FDA arise, however, in drawing the line between falsity and mere "puffing." As with misleading claims, the FDA has done very little in this area of regulating false representations. Only now, as the Advisory Panels complete their reports, is the FDA beginnning to face the issue of how to regulate false representations.

It is a violation of Federal Trade Commission regulations to market a product that is different from that being advertised, even if the consumer is *no worse off* or *even better off* for having purchased it.[59] Although insuring the truthfulness of medical claims for OTC drug products is a central goal of the FDA,[60] it has yet to develop a policy on truthfulness equal to the Federal Trade Commission's policy.

The most prevalent medically inaccurate claim in the OTC drug context is the claim with no statistical support. Generally, the product

58. *See, e.g.*, FTC v. Colgate-Palmolive Co., 380 U.S. 374 (1965).
59. FTC v. Algoma Lumber Co., 291 U.S. 67, 78 (1934).
60. *See* 21 U.S.C. §§ 352(a), (f) (1976).

will be safe and effective for some claimed use, and the label will list that use plus others for which the product may or may not be effective. For example, one Panel rejected claims that a bronchodilator was effective for the "relief of hayfever;" that an anticholinergic "clears nasal passages, opens airways;" that an antihistamine "decreased nasal obstruction;" and that oral nasal decongestants could "overcome drowsiness caused by antihistamines."[61] The objection to such claims is that there is no objective means to measure their veracity. For example, relief of feelings of depression may be impossible to determine objectively.

A claim may also be effectively false because it exaggerates the degree of expected therapeutic benefit from an OTC drug product. One advisory Panel rejected the term "tranquilizer" as an indication for both nighttime and daytime sedatives. The Panel concluded that the term "tranquilizer" is misleading because it "promises a quantitatively different effect than that which an OTC drug is able to provide. Tranquilizer is a term properly identified with a medically prescribed psychotropic drug which is available by prescription and should in fact only be available by that source."[62] The Panel chose instead to divide the class into two groups: "daytime sedatives" and "nighttime sleep aids."[63]

Claims may be false because they have no medical meaning at all. One Panel discovered numerous claims of this type appearing on OTC cold product drug labels. That Panel rejected claims containing pseudo-medical terms such as "antiallergic," and pseudo-medical activities, such as "gets at the root of," "fights," "wake-up," and "multiaction."[64] Claims which use such terms create and perpetuate confusion and misinformation concerning proper drug use.

Claims which encourage erroneous conclusions about the causes of certain conditions create similar misconceptions. The Antacid Panel concluded "that claims or indications which link certain signs and symptoms, such as 'sour breath,' 'upper abdominal pressure,' 'full feeling,' 'nausea,' 'stomach distress,' 'gas,' 'indigestion,' 'upset stomach,' and 'excessive eructations' with normal or hypernormal gastric acidity, are unproven since the relationship of such signs and symptoms to gastric acidity is unknown or dubious and there is inadequate and unreliable scientific evidence to support these claims."[65] Such claims or indications encourage the user to draw conclusions as to the cause or intermediation of such symptoms—conclusions that even the medical profession is incapable of drawing at this time.

Claims which explicitly or implicitly indicate treatment for condi-

61. 41 Fed. Reg. 38,312-424 (1976).
62. 40 Fed. Reg. 57,292, 57,293 (1975). Claims rejected on similar grounds include "cathartic" and "purgative." 40 Fed. Reg. 12,902, 12,904 (1975).
63. 40 Fed. Reg. 57,292, 57,293 (1975).
64. 41 Fed. Reg. 38,312, 38,337 (1976).
65. 38 Fed. Reg. 8714, 8722-23 (1973).

tions for which only symptomatic relief is available are clearly medically inaccurate. One Panel determined that the "common cold" was such a condition. The Panel found that "there is no demonstrated safe and effective OTC active ingredient or combination of active ingredients acceptable for specific treatment of the 'common cold,' " and therefore recommended that "product names or labeling claims that infer or suggest a direct relationship to the 'common cold,' e.g., 'cold medicine,' 'cold formula,' 'for relief of colds,' should not be allowed. Such statements may mislead the consumer into believing that these products prevent, treat, or cure the disease itself."[66]

Claims which "guarantee" therapeutic results are another type of false medical claim. The Nighttime Sleep Aid Panel concluded that " 'guaranteed' is misleading and a false promise if used in a general way such as 'guaranteed fast-acting.' No drug helps 100 percent of the time. The Panel believes that the word 'guarantee' should be prohibited in regard to medical claims."[67]

Other claims which may be medically false are those that lead the consumer to believe that the drug will induce a "natural" condition. The Nighttime Sleep Aid Panel rejected the claims "natural sleep," "normal sleep" and "sound sleep" as misleading because a nighttime sleep aid "is an exogenous non-naturally occurring agent introduced into the body. Hence, the body is obviously not entirely in its 'natural' state during drug-induced sleep."[68] The Laxative Panel also rejected the term "natural" in describing the therapeutic action of laxatives, concluding that "the suggestion that a laxative is somehow 'natural' because of its source is misleading because it implies that the product or ingredient is a 'natural way' to induce laxation. It is not considered 'natural' to take any laxative."[69]

To alleviate the problems caused by false representations, the FDA should require that all information relating to use be reviewed prior to marketing and then ban, at that time, any terms found to be false. All other claims which are determined to be false should be prohibited. The FDA should establish a separate procedure to review again claims that are discovered to be false after the product has been approved for

66. 41 Fed. Reg. 38,312, 38,377 (1976). Claims rejected on similar grounds include "eliminates" and "treatment." 45 Fed. Reg. 35,576, 35, 602 (1980). Similar to claims which promise treatment for an incurable condition are claims which promise treatment for a condition which cannot exist. The Anorectal Panel, in rejecting such a claim, stated that "[b]ecause there are no sensory pain-nerve fibers present in the rectal mucusa, words and phrases such as 'temporarily relieves rectal itching' and 'temporarily relieves rectal irritation' are clearly inappropriate as there is no feeling of pain or itch in the rectum."

67. 40 Fed. Reg. 57,292, 57,297 (1975). False claims may also exist in situations in which a claim is made for a particular ingredient in such a way that the consumer is led to believe that the claim applies to the entire product. The CCABA Panel rejected such a claim made for the safety of a nasal decongestant ingredient. The Panel stated that the "term 'non-irritating base' is unacceptable because it may encourage a misleading conclusion about the safety characteristics of the total product."

68. 40 Fed. Reg. 57,292, 57,297 (1975).

69. 40 Fed. Reg. 12,902, 12,905 (1975). The Anorectal Panel rejected the claim "natural healing is encouraged" on similar grounds. 45 Fed. Reg. 35,576, 35,602 (1980).

market. However, the burden of proof should then shift to the FDA to show the claim's falsity.

In addition to the above-mentioned false representations, there are two special forms of false representation which regularly occur on OTC drug labels—claims connected to reformulated products and claims connected to products for which there is insufficient data to permit final classification (Category III products). These two forms will be discussed separately below.

Drug Reformulation. As a result of the FDA's review of all OTC drugs, many products have been identified that had little or no evidence of effectiveness for their stated uses. Many of these products have not been removed from the market. Rather, they have been reformulated with ingredients which have been shown to be safe and effective. At this time the FDA does not require that reformulated products have different trade names or that the public be notified that those products retaining their old names have been reformulated.[70]

Allowing the marketing of reformulated OTC drugs under their original trade names without disclosing this fact on the labels can pose an extreme hazard to consumers. This lack of information can severely hamper treatment of common poisonings that arise from such products. The problem may arise because either the consumer or the physician has been misled. For example, a situation could occur where an overdose has been taken of a reformulated sleep-aid product that had contained methapyrilene (a recently determined unsafe ingredient) prior to reformulation. The treating physician may consult a medical reference book that lists, under the product's name, methapyrilene as an ingredient. He would then treat for an overdose of methapyrilene, rather than the ingredient that was actually taken. Even if he knows that the product has been reformulated, he might not be able to determine whether the patient took the old product with methapyrilene or the new one. Requiring reformulated products to be renamed would let both doctor and patient know exactly what was taken.[71]

Even in situations where reformulation does not cause life-threatening hazards, it can result in consumer exposure to new or unanticipated side effects of drug use. The advisory reports demonstrate that many ingredients which provide equivalent therapeutic results produce very different types of side effects. For example, the Antacid Panel found

70. The only official statement the FDA has made regarding its policy towards reformulation was in its General Comments Section explaining its procedures for classification of OTC drugs: "Any drug product which is on the market and which is reformulated and/or relabeled within the limits of the final monograph will not lose its trademark as long as its continued use is not misleading. Transitional labeling may be required where close questions arise." 37 Fed. Reg. 9466 (1972).

71. Similar examples where reformulation may cause confuson on the part of the physician include the reformulation of Allerest Tablets, Bromoseltzer, Cope, Liquiprin, and Nervine Effervescent Tablets (source testimony before the FTC Hearings on Over-the-Counter Drug claims by California Citizen Action Group: Public Record 215-51).

that among therapeutically similar ingredients, some had so few side effects that warnings were not necessary,[72] while other had toxic effects.[73] While none of these side effects was likely to be life-threatening, the FDA concluded that consumers should be aware of their existence via labeling warnings.[74] However, consumers who have continued to use a particular OTC product over a period of time may not be aware that a product has been reformulated in the absence of affirmative disclosure on the label. There may be no reason for a consumer who has read the product label once to continue to read it every time a new purchase is made of a facially identical drug.

Furthermore, even if a consumer were to read the list of ingredients placed on a reformulated product label, that consumer would be unlikely to know that those ingredients are different from the old ingredients unless the difference is brought to his attention. At present, although the new ingredients are required to be listed on the product label,[75] there is no requirement that the consumer be informed of the change.

The lack of this requirement may also be costly to the consumer. A company which reformulates a product and markets it under the same trade name unfairly encourages old customers to purchase the new product on the assumption that it is still the same as before. When the difference becomes apparent, the customer could find out that he has wasted his money.

One solution to this problem of potentially misinforming consumers and physicians would be to adopt regulations prohibiting labeling reformulated products under the same name. This does not mean that the previous brand name would have to be completely obliterated. It would merely be required to be altered in such a manner as to clearly identify the reformulated product as different from its predecessor. At a minimum, some warning should be attached informing consumers of the change and its possible effects.[76]

Category III. In 1972, under the initial procedures established to implement the FDCA, the FDA classified each drug ingredient reviewed according to one of three classes: Category I ingredients are those generally recognized as safe and effective; Category II ingredients are those not generally recognized as safe and effective and that should no longer be used in marketed products; and Category III are those ingredients for which there is insufficient data to permit final classifica-

72. *E.g.*, aluminum, 38 Fed. Reg. 8714, 8717-18 (1973).
73. *E.g.*, potassium, 38 Fed. Reg. 8719 (1973).
74. *Id.*
75. 21 C.F.R. § 330.10 (1981).
76. Trademarks and trade names are clearly important in the OTC drug industry considering the large amount of money spent by drug manufacturers in establishing brand recognition. Therefore, if the manufacturers were to choose between changing the trade name or noticing the reformulation, they would choose the latter.

tion.[77] This categorization scheme had the effect of allowing any product with a Category III condition to remain on the market (after the final regulations had been issued) without notification to the public.[78]

This procedure was criticized by various consumer groups. In *Cutler v. Kennedy*, a consumer group challenged the FDA's procedure of permitting the continued marketing of certain products while testing of their ingredients was still being conducted.[79] The consumer group charged that the FDA policy did not comply with the FDCA since that Act does not provide for interim classifications such as Category III.[80] In July of 1979 the judge in that case (John Sirica) held in favor of the consumer group.[81] The case became binding on the FDA when it decided not to appeal the decision.

In his decision, Judge Sirica held that the FDA's OTC regulations permitting drugs with Category III conditions to be marketed after the final regulations were issued was illegal under the provisions of the FDCA.[82] To effectuate his decision, Judge Sirica enjoined the FDA from implementing any portion of the disputed regulations that authorized the marketing of Category III drugs after final regulations were issued.[83]

The FDA has responded to the *Cutler* decision by proposing a period of time after advisory Panels have completed their review, but before any final regulations have been published, during which manufacturers may submit new data and information to support approval of Category III products.[84] In effect this response has caused no change in FDA procedures since the *Cutler* lawsuit except to cause a delay in issuing final regulations. The public is still not aware that some products are being allowed to be marketed that have not been approved by the FDA.

Since there can be no official basis from which to conclude that Category III products will perform as claimed, to permit the marketing of these products to consumers without notification of that fact is false or at least misleading labeling, and should be considered so by the FDA. Because we are dealing in products which directly affect the health and safety of the consumer, mandatory notice of this fact on OTC drug product labels seems even more compelling. Drug manufacturers have been on notice since the passage of the FFCA Amendments of 1962 that the safety and effectiveness of their OTC drug products must be demonstrated to the FDA.[85]

77. 21 C.F.R. §§ 330.10(a)(5)(ii) to .10(a)(5)(iii) (1981).
78. 21 C.F.R. § 330.10(a)(13) (1981).
79. Cutler v. Kennedy, 475 F. Supp. 838 (D.D.C. 1979).
80. *Id.* at 848.
81. *Id.* at 855.
82. *Id.*
83. *Id.* at 857.
84. 45 Fed. Reg. 31,422 (1980). The proposal was later adopted. 46 Fed. Reg. 47,730 (1981).
85. *See* note 2, *supra*.

Truthful Representation Encouraging Inappropriate Use

In an effort to increase product sales a manufacturer may encourage the use of a product for a condition for which it was not approved. This practice is considered misbranding and is clearly unacceptable. A manufacturer may accomplish this type of misbranding without actually claiming specific unapproved indications, but rather by using truthful representations out of context. Such subtle misbranding is very hard to detect. This section will elucidate several different forms of this method of product mislabeling.

A manufacturer may produce a misleading label and justify it by contending that it is merely using true facts in a manner favorable to it. After all, the manufacturer argues, it is not required by the FDA to cast information communicated on drug labels in its worst light. One way that manufacturers distort information in this way is by *not* making reference to any specific illness or condition when designating the uses of an OTC drug product.[86]

Some consumers will then assume that the product is appropriate for the condition they are seeking to remedy, while the product is actually not an effective or safe remedy for that condition.

Another way in which an OTC drug product label may promote inappropriate drug use is when it contains claims for treatment of a condition that usually requires diagnosis and care by a physician. For example, the Anorectal Panel expressed its concern "with the use of words or phrases describing anorectal conditions that are not easily diagnosed by the consumer and therefore are not appropriate for the OTC market, such as 'anal eczema' and 'psoriasis.' "[87] Furthermore, the Panel was aware of current labeling that instructs the consumer to use the product "before or after hemorrhoidectomy," "for anorectal surgical wounds," "episiotomies," or "sclerosing therapy." The Panel concluded that "such labeling is not appropriate for consumers because these conditions are best treated under the advice and supervision of an attending physician."[88]

The Internal Analgesic Panel solved this problem in a different way by recommending the prohibition of such claims. The Panel gave the following reasons for its approach:

> Since OTC drugs are meant to be used only for the temporary relief of symptoms, the labeling should not indicate or imply the preparation

86. The Nighttime Sleep Aid Panel discovered such a problem. 40 Fed. Reg. 57,292, 57,318, 57,321 (1975).

87. 45 Fed. Reg. 35,576, 35,602 (1980).

88. *Id.* In rejecting the claim "control of minor bleeding" for vasoconstrictor drug products, the Panel emphasized the danger of requiring consumers to distinguish between the bleeding associated with minor abrasions and the bleeding which indicates early stages of more serious lesions such as fissures and carcinomas. The Panel noted that "[e]arly detection of carcinoma is still the best available means of control, and this is best encouraged, in the opinion of the Panel, by directing the user of anorectal drug products to consult the physician if bleeding occurs for any reason." 45 Fed. Reg. 35,576, 35,626 (1980).

> is for the treatment of disease entities, such as arthritis. . . . Self-medication may lead to irreversible joint damage if taken in inadequate dosage intermittently for pain relief over prolonged periods by individuals with some forms of arthritis. Since the most common forms of arthritis, rheumatoid arthritis and osteoarthritis, are chronic diseases, "temporary" relief by OTC analgesic doses is inappropriate therapy for these diseases. . . . The Panel believes that any labeling for diseases such as these which require medical intervention may mislead the consumer who attempts to self-diagnose and self-treat serious diseases. Therefore, the Panel strongly recommends that product names or labeling that infer or suggest the use of these products for specific diseases requiring prior diagnoses by a physician should not be allowed. Any reference to "arthritis," "arthritis strength," "arthritis pain formula," "rheumatism preparation," etc., in product names or labeling is unacceptable to the Panel.[89]

Claims that downplay the risks of OTC medication should also be of concern to the FDA. Claims of this sort can lead to casual use which, in turn, can easily lead to misuse. Claims that promote casual drug use create and perpetuate irresponsible self-medication by lulling the consumer into a false sense of security in the safety and effectiveness of OTC drugs.

For example, the Opthalmic Panel found that "[p]hrasing that promises general benefits of good health or well being or warns against the dangers of physiological states such as 'fatigue,' 'tired eyes' or 'eyes over forty' " are unacceptable.[90] Along this vein, the Panel rejected claims which indicate use for normal visual activities such as "watching television," "reading," and "close work" or that suggest opthalmic products "for continuous everyday use," "for improvement of tired eyes" or "for use before putting on makeup."[91] Labeling claims of this type are particularly pernicious and should be prohibited by the FDA.

False Differentiation

Product differentiation is a commonly employed marketing technique. It is used to distinguish the product being promoted from other like products in an attempt to direct the purchaser's selection towards the promoted product. Mislabeling can occur if there is no sound medical reason to differentiate the products.

The manufacturer may claim general product superiority or specific superiority in comparison with other like products. These claims of product superiority falsely differentiate products when documentation of such superiority does not exist. For example, the Internal Analgesic

89. 42 Fed. Reg. 35,346, 35,355 (1977).
90. 45 Fed. Reg. 30,002, 30,023 (1980).
91. *Id.* at 30,023-24. As another example, the Laxative Panel warned against allowing language that "promises general benefits in good health or well being." The Panel specifically banned the term "irregularity" from laxative labeling "because 'regularity' of bowel movement is not essential to health or well being" and therefore 'irregularity' as an indication for use is misleading." 40 Fed. Reg. 12,902, 12,905, 12,912 (1975).

Panel found general claims of product superiority, such as "special pain relieving formula" and "enhanced relief of pain," to be "confusing and misleading to the consumer" and therefore unacceptable.[92]

The CCABA Panel discovered another form of this misleading practice. Certain manufacturers equated an increased quantity of an active ingredient with an increased therapeutic effect. The Panel concluded that there was "no justification for claiming more activity per dose for one Category I ingredient over another because there is no scientific merit from a therapeutic point of view between a product containing 15 mg. of drug A and another containing 30 mg. of drug B if they are similarly effective. Unsubstantiated claims for 'extra strength' or 'contains more active ingredient per dose' or 'higher dose level' or 'stronger than' are therefore misleading."[93]

The CCABA Panel also rejected misleading superiority claims which "state or imply actions peculiar to a particular product, when in fact those claims are applicable to all OTC drug products or all Category I ingredients of the same pharmacological group."[94] Insofar as the claim goes to the safety and effectiveness of the product, it is verifiable and should be prohibited if contrary to or not supported by information made available to the FDA.

Claims which falsely imply that competitor's products have certain undesirable qualities should also be found deceptive. The Anorectal Panel rejected claims such as "contains no narcotic, anesthetic or habit-forming ingredients," "without the use of narcotics," or "contains no stinging, smarting, astringents" because these claims imply "that other products are narcotics, anesthetics, or astringents and are harmful without any evidence that this is so."[95] The Panel also rejected "medicinal," "recommended by physicians," "recommended by doctors," or "doctor tested" as misleading "because these terms suggest that other products are not medicine or that other products are of no value because physicians do not recommend the other products or that all physicians recommend these products."[96]

Claims which imply that particular therapeutic actions are peculiar to certain products, when in fact all similar products act in the very same way, are also misleading. For example, the CCABA Panel rejected the claims "travels through the bloodstream" and "works internally" because "[a]ll drugs taken internally 'work internally' and virtually all drugs taken internally are absorbed into the bloodstream. Thus, these claims are also not appropriate in OTC labeling."[97]

Another way in which a product may be promoted truthfully and

92. 42 Fed. Reg. 35,346, 35,435 (1977).
93. 41 Fed. Reg. 38,312, 38,337 (1976).
94. *Id.*
95. 45 Fed. Reg. 35,376, 35,602 (1980).
96. *Id.*
97. 41 Fed. Reg. 38,312, 38,337 (1976).

yet be misleading is by the use of specific indications which are merely subparts of a larger, general condition. An example of this technique was discovered by the Internal Analgesic Panel. The labels of certain internal analgesic products bore claims for a variety of specific types of pain. The Panel found that internal analgesics were equally effective on various types of pain regardless of the source. The Panel concluded that "the use of only a partial list of some claims such as 'low back pains, due to over-exertion' in the labeling of one manufacturer's product and the omission of these claims from the labeling of the same drug by another manufacturer would mislead the user into believing the preparations are different."[98] The Panel decided to allow internal analgesic products to only bear the indication: "For the temporary relief of occasional minor aches, pains and headache."[99]

As was suggested for those claims encouraging inappropriate use, claims which attempt to falsely differentiate OTC drug products by the use of truthful representations should be prohibited. This should be accomplished by means of regulations that can be applied equally to all types of OTC drugs.

CONCLUSION

The FDA is in the middle of implementing a massive review of all OTC drug products. Those products found to be unsafe, ineffective, or misbranded are to be removed from the marketplace. However, the positive effects of this program may never be felt by the public if the FDA does not establish an effective uniform program to prohibit deceptive and misleading labeling claims. Labeling information and format should not be allowed to vary according to the wishes of manufacturers but should be limited to FDA approved terminology and format. In addition, the FDA should delineate the various types of deceptive labeling and prohibit their use. At the very least this should include prohibiting specific forms of misleading claims, false claims, claims which promote inappropriate use, and claims which falsely differentiate similar products.

98. 42 Fed. Reg. 35,346, 35,435 (1977).
99. *Id.* at 35,422. The Panel disallowed such varied and specific indications as: "nervous tension headache," "toothache," "pain of neuralgia," "pain of flu," "pains of minor injury," "body aches," and "minor pain of arthritis."