Cleveland State Law Review

Volume 20 | Issue 2 Article

1971

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FEDERAL TRADE COMMISSION regulation of pharmaceutical advertising is a subject of considerable current interest. The criteria for determining the acceptability of these advertisements are still evolving, and a definitive set of rules has not yet been fully articulated. Nevertheless certain trends are developing.[1] One of the major objectives of this paper is to predict the ultimate form of these rules. Based upon consideration of a limited number of very recent cases, discussed in detail in this paper, the rules which appear to be evolving are three:

1. Every individual statement contained in the advertisement must be true.[2]
2. Even if each individual statement is, itself, technically and literally true, the overall impression created by the advertisement, when read by the audience toward whom it is directed, must not be false or misleading.[3]
3. Even if each individual statement is technically and literally true, where additional information is necessary in order to properly evaluate the significance of those statements, affirmative disclosure of that information will be required.[4]

The implications of this evolutionary process are probably far broader than merely its application to pharmaceutical products. The rules applied to pharmaceuticals today are likely to be applied to other products tomorrow.

Pharmaceutical advertising typically takes a variety of forms—the use of mass media, distinctive labeling, direct mail, and verbal presentations by "detail men." It is directed to two distinct audiences—the physician and the layman; and, to further complicate matters, covers two vastly different types of products—prescription and over-the-counter drugs.[5] The scope of the present paper will be limited to that portion

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1 Kintner, The Revitalized Federal Trade Commission: A Two-Year Evaluation, 30 N.Y.U. L. Rev. 1143, 1148 (1955); F.T.C. v. Sterling Drug Inc., 317 F. 2d 669 (2d Cir. 1963), initial decision dismissing the complaint, 3 C.C.H. Trade Cas. Reg. Rep. 16, 496 (1963).

2 Opinion on interpretation of an advertisement in Heintz W. Kirchner, F.T.C., Docket No. 8538 (1963); 11 N.Y.U. L. Rev. 663 (1934); 82 U. Pa. L. Rev. 664 (1934); 43 Yale L. J. 1338 (1934).

3 *Id.*

4 *Id.*

5 A "drug" is defined by the Federal Food, Drug and Cosmetic Act as any article recognized by certain official compendia or "articles intended for use in the diagnosis,

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of the broad subject which is congruent with the area regulated by the Federal Trade Commission: mass media advertising of non-prescription drugs to the general public.[6]

Historically, the people of the United States have always favored self-medication. Indeed, until the passage of the Food, Drug and Cosmetic Act[7] in 1938, any drug could be advertised and sold directly to the consuming public without a physician's prescription.[8] The existence of a strong continuing Congressional policy in favor of self-medication is evidenced by the fact that the 1938 Act treated the new category of prescription drugs as an exception to the general category, having special requirements, rather that exempting over-the-counter drugs from prescription requirements.[9] The courts have generally assumed the existence of this policy without question.[10]

It must be recognized, however, that self-diagnosis and medication are not without pitfalls. As the frontiers of medical knowledge advance, the complexities of the human mechanism become more and more ap-

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cure, mitigation, treatment or prevention of disease . . . and articles intended to affect the structure or any function of the body . . . ," 52 Stat. § 1041 (1938), 21 U.S.C. § 321(g) (1964). The phrase "prescription drugs" is used in this paper synonymously with "ethical drugs" and is defined by the Act as a drug which, "because of its toxity or other potentiality for harmful effects, or the method of its use, is not safe for use except under the supervision of a (licensed) practitioner . . . ," 52 Stat. § 1050 (1938), 21 U.S.C. § 353(b) (1964). The phrase "over-the-counter (OTC) drugs" is not defined by the Act but, by implication, encompasses all non-prescription drugs.

[6] The Wheeler-Lea Amendment of 1938 to the Federal Trade Commission Act, 38 Stat. § 717 (1914), 15 U.S.C. § 41 (1963) et seq., vested the Federal Trade Commission with the responsibility for regulation of all advertising pertaining to foods, drugs, curative devices, and cosmetics:

> "Dissemination of false advertisements—unlawfulness.
>
> (a) It shall be unlawful for any person . . . to disseminate . . . any false advertisement . . . by any means, for the purpose of inducing . . . the purchase of foods, drugs, devices, or cosmetics." 15 U.S.C. 41, § 12 (1963).

Labeling for all drugs, and advertising directed to members of the medical profession, however, is specifically exempted by section 15 of the Act:

> The term "false advertisement" . . . means an advertisement other than labeling. . . . No advertisement for a drug shall be deemed to be false if it is disseminated only to members of the medical profession . . . (and conforms to the requirements of the Food, Drug and Cosmetic Act) 15 U.S.C., 41 § 15 (1963).

Labeling, which is defined as written, printed, or graphic matter directly accompanying the drug, in, or together with, its sales package, and advertisements to the medical profession are regulated by the Food and Drug Administration pursuant to the powers vested in it by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (1961), et seq. Since prescription drugs may not be advertised except to licensed practitioners, this effectively places sole responsibility for regulation of these items solely in the hands of the FDA. The details of regulation within FDA's authority is beyond the scope of the present paper, but the detailed and complex regulations in this area may be found at 21 CFR § 1.100 (1970), et seq.

[7] 52 Stat. § 1 (1938), et seq. 21 U.S.C. § 301 (1964) et seq.

[8] Digest of the New Federal Food, Drug and Cosmetic Act, U. S. Food and Drug Admin., June 27, 1938.

[9] *Id.*

[10] Cf., for example, J. B. Williams Co., Inc. v. F.T.C., 381 F. 2d 884 (6th Cir. 1967): "We can find no Congressional policy against self-medication on a trial and error basis. . . . In fact Congressional policy is to favor self-help."

parent. In these days of radioactive tracers, biochemical analysis, and multidisciplined clinical studies, the cure-all Indian Snake Oil remedy has lost much of its appeal. We have come to recognize the fact that a misleading statement regarding the safety or efficacy of a drug may be far more than an economic cheat; it may be positively harmful in that it can encourage the sick individual to forego needed medical attention.[11]

The public is particularly poorly equipped to evaluate claims made for pharmaceutical preparations because any such evaluation must be based upon sophisticated scientific knowledge. When the layman is told, "hospital tests prove that Bio-Dyne (in Preparation-H) rushes the body's healing oxygen to the affected area," [12] how can he assess the meaning of this statement? What were the nature and scope of the hospital tests? Do they conform to modern standards of adequate clinical studies? What is Bio-Dyne? Does it really increase the oxygen content of the tissues? Even if it does, what has oxygen to do with the healing of hemorrhoids? Is it effective in all cases? What other treatments are available? The answers to these, and many other questions, are essential to a realistic evaluation of the advertisement, yet the layman is unlikely to know enough to ask them, much less where to obtain the answers.

The Preparation-H advertisement quoted above is a good example of the classical problem in the regulation of pharmaceutical advertising —misrepresentation by overt statement. The Federal Trade Commission and the courts have had little difficulty in recent years in suppressing advertisements in this category. For example, despite, the court's traditional reluctance to interfere with long established trade names,[13] the Ninth Circuit Court of Appeals did not hesitate in enforcing an FTC order banning the use of the word "Liver" in the trade name "Carter's Little Liver Pills" and any advertising of the product when the FTC showed that the product contained no liver or liver extract, and had no effect on the function of the liver.[14] Since that decision, the product has been known as "Carter's Little Pills." In another case, the Fifth Circuit found that a statement that "today baldness is unnecessary . . . hopeless cases are few . . . ninety-five percent of all cases of hair loss came within the scope of . . . treatment" is false and misleading and and it is within the power of the FTC to prohibit its uses in advertising.[15] Again, where substantial medical evidence demonstrates that 90 to 95 percent of all baldness results from causes other than microbial infec-

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[11] *Cf.*, for example the testimony in the Krebiozen case, Ivy v. Katzenbach, 351 F. 2d 32 (7th Cir. 1965), cert. denied 382 U.S. 958 (1965).

[12] Radio advertisement for Preparation-H, a hemorrhoid remedy manufactured by American Home Products, Inc.

[13] Elliot Knitwear, Inc. v. F.T.C., 266 F. 2d 787 (2d Cir. 1959).

[14] Carter Products, Inc. v. F.T.C., 268 F. 2d 461 (9th Cir. 1959) (C.A. 9, 1959).

[15] Keele Hair & Scalp Specialists v. F.T.C., 275 F. 2d 18, 1960 Trade Cases 69615 (5th Cir. 1960).

tion, the manufacturer cannot exhort the public to "save your sick hair from trouble-breeding bacteria." [16] The prohibition of a claim that a "Rejuvenesence Cream" brings to the user's face "the clear radiance . . . the petal-like quality and texture of youth" and that it restores "natural moisture necessary for a live, healthy skin" when, in fact, the cream had no effect on the structure or conditions of the skin, was held to be clearly within the FTC's regulatory powers.[17] Similarly, a representation that "Glantrex" was a quick acting remedy for malaria, when its composition was such that it could not be expected to produce any therapeutic effect upon any known disease, was found to be false and misleading and could be prohibited.[18] Many other similar cases might be cited.

Even when every statement made in the advertisement is, in itself, literally true, the total impact of the advertisement, when read by the audience toward whom it is directed, may not be false and misleading.[19] Thus, an advertisement for vitamin tablets which conveys the impression that they will prevent or cure a variety of illnesses can be enjoined by the Federal Trade Commission despite the fact that the advertisement does not contain an explicit statement to that effect.[20] An advertisement for an aspirin product for the "treatment" of arthritis, rheumatism, swollen joints, neuritis, neuralgia, sciatica, and lumbago was ordered discontinued because the use of the word "treatment" conveyed the impression that the preparation would cure or alleviate these conditions when, in fact, it could do no more than relieve minor pains associated with them.[21] Several cases have held that the use of the term "remedy,"

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[16] Ward Laboratories, Inc. v. F.T.C., 276 F. 2d 952, 1960 Trade Cases 69690 (2nd Cir., 1960).

[17] Charles of the Ritz Distributors Corp. v. F.T.C., 143 F. 2d 696, 1944-45 Trade Cases 57267 (2nd Cir., 1944).

[18] George G. Neff v. F.T.C., 117 F. 2d 495 (4th Cir., 1941).

[19] On March 19, 1969, the Federal Trade Commission published (34 Fed. Reg. 5387) the text of its Proposed Guides for Advertising Over-the-Counter Drugs, 16 CFR § 249 (Proposed). While these proposed guides have never been promulgated as final regulations, they are valuable as an indication of the thinking of the Commission:

"General Principles . . .

(a) The important criterion in determining whether an advertisement is false and misleading is the net impression which it is likely to make on the general population. A false impression can be conveyed by words and sentences which although literally and technically true are formed in such a setting as to mislead and deceive. . . .

(c) The Commission will draw upon its own experience in interpreting advertising. It may do so without the aid of consumer testimony either as to express or implied representations. It may determine that advertising is misleading on the basis of its visual examination of exhibits even though members of the public may testify that they were not deceived by it. An advertisement will be regarded as deceptive if one of two or more permissible, reasonable interpretations is false or misleading." 21 CFR § 249.2.

[20] Stanley Laboratories, Inc. v. F.T.C., 138 F. 2d 388 (9th Cir., 1943).

[21] F.T.C. Docket Numbers 5712 and 5881.

when used in advertisements for cold preparations, conveys the impression that the drug will cure colds, when they can do no more than relieve the symptoms of a cold.[22] The trade name "Outgrow" in advertisements for an ingrown nail treatment preparation, without a clear and conspicuous disclaimer to the effect that the preparation has no effect, in any way, on the growth, shape or position of the toenail, was held to be false and misleading.[23]

> The Federal Trade Commission Act . . . was not made for the protection of experts, but for the public—that vast multitude which includes the ignorant, the unthinking and the credulous . . . . and the fact that a false statement may be obviously false to those who are trained and experienced does not change its character, nor take away its power to deceive others less experienced . . . The important criterion is the net impression which the advertisement is likely to make on the general populace.[24]

The far more difficult problem is that of misrepresentation by omission of essential information, rather than misrepresentation by overt statement. The question of whether the Federal Trade Commission can require the pharmaceutical advertiser to include *all* of the information necessary for the reader to intelligently evaluate the statements made in his advertisement has claimed the attention of the Federal Trade Commission and the courts in recent years and will receive detailed attention in the present paper. While the law in this area appears to be evolving very rapidly, and no case presenting the exact question has yet reached the Supreme Court for resolution of the conflicts between various circuits,[25] I shall attempt to describe the trends I believe are exhibited by these cases.

The "classical" approach to the problem of misrepresentation by omission of essential information is illustrated by *Alberty v. Federal Trade Commission.*[26] Petitioners manufactured a vitamin-mineral supplement named Oxorin Tablets. A typical advertisement for Oxorin Tablets reads:

> Pep up your blood! Iron . . . (is) a principal factor in Red Blood Cells . . . The disease fighting units of the blood. When you are weary, tired, run-down, just dragging yourself around with no ambition left, when every effort you make seems to leave you weak and spent, then try Oxorin Tablets, a tonic for the blood!

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[22] Justin Haynes & Co. v. F.T.C., 105 F. 2d 988 (2nd Cir. 1939); Koch v. F.T.C., 206 F. 2d 311 (6th Cir. 1953). Consolidated Royal Chemical Co. v. F.T.C., 191 F. 2d 891 (7th Cir. 1951).

[23] Federal Trade Commission Docket Number 8478.

[24] Charles of the Ritz Distributors Corp. v. F.T.C., *supra,* n. 12.

[25] The accuracy of my "crystal ball" may soon be put to the acid test. American Home Products, Inc. v. F.T.C. has been appealed to the Supreme Court. Food, Drug and Cosmetic Reports ("The Pink Sheet"), Trade & Government Notes, p. 6, September 22, 1969.

[26] 180 F. 2d 36 (D.C. Cir. 1950), cert. den. 340 U.S. 818, 71 S. Ct. 49 (1951).

After hearing extensive medical testimony, the Federal Trade Commission found that

> the condition of lassitude is caused less frequently by simple iron deficiency anemia than by other causes;
>
> where said condition is due to other causes, medical attention is highly desirable;
>
> the preparation "Oxorin Tablets" will (not) have any therapeutic effect . . . except in cases of simple iron deficiency anemia.[27]

Based upon these findings, the Commission ordered the petitioner to disclose, in his advertising, the facts that "Oxorin Tablets" would be effective only in simple iron deficiency anemia and that most cases of tiredness and lassitude resulted from causes other than this condition.[28]

The court found that the Federal Trade Commission lacked the power to compel this type of disclosure, in that, it had failed to find a statement which is misleading because of the consequences from the use of the product, or a statement which is misleading because of the things claimed in the advertisement. The realm of the F.T.C. is the negative function of preventing falsity and not the affirmative function of requiring, or encouraging additional interesting, and perhaps useful information which is not essential to prevent falsity.[29] The court refused to enforce the Commission's order.

In distinct contrast, from what I have labeled the "transitory phase," is the Sixth Circuit's opinion in the *J. B. Williams* case.[30] Again, a Federal Trade Commission order requiring affirmative disclosure in vitamin-mineral tonic advertising was contested. The advertisements in question were similar to those of the *Alberty* case:

> If you often have that tired and run-down feeling . . . . and if you take vitamins yet you still feel worn-out, remember . . . . your

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[27] Federal Trade Commission Docket Number 5101.

[28] In, Kerrany, F.T.C., 265 F. 2d 246 (10th Cir. 1959), the Commission ordered petitioners to cease and desist selling refined oil for lubrication without disclosing to purchasers that the oil had been previously used. In affirming the order, the court argued,

> "The public is entitled to know the facts with respect to lubricating oil sold by the petitioners being produced from previously used oil and then make its own choice with respect to purchasing such oil or oil produced from virgin crude, even though the choice is predicated at least in part upon ill-founded sentiment, belief, or caprice. * * * And therefore the practice of the petitioners in marketing their re-refined lubricating oil in containers indistinguishable from those used generally to market lubricating oil refined from virgin crude, without any disclosure that it is made from previously used oil, constitutes a deceptive practice within the intent and meaning of section 5(a) of the Federal Trade Commission Act * * *." See also, Mary Muffet, Inc. v. F.T.C., 194 F. 2d 504 (2d Cir. 1952); Theodore Kagen Corp. v. F.T.C., 283 F. 2d 371 (D.C. Cir. 1960); Mohawk Refining Corp. v. F.T.C., 263 F. 2d 818 (3d Cir. 1959); Royal Oil Corp. v. F.T.C., 262 F. 2d 741 (4th Cir. 1959); Rhodes Pharmacal Co. v. F.T.C., 208 F. 2d 382 (7th Cir. 1953); Carter Products, Inc. v. F.T.C., 268 F. 2d 461 (9th Cir. 1959).

[29] *Supra,* n. 26 at 37-38.

[30] *Supra,* n. 10.

> trouble may be due to iron-poor blood. And vitamins *alone* can't build up iron-poor blood. But GERITOL can! . . . GERITOL begins to strengthen iron-poor blood in 24 hours . . . You'll *feel stronger fast* in just seven days . . . .[31]

The court reviewed the medical testimony before the Commission in detail, and agreed with the Commission's findings that the symptoms described in the advertisement occur in many diseases and that most of these are unrelated to iron deficiency.[32] Indeed, even where iron deficiency is implicated, tiredness and lassitude would not normally appear until the anemia became severe and, at that point, a simple iron tonic would be ineffective as a remedy. The advertisements, the court concluded, deceptively created the impression that a tired and run-down feeling was universally symptomatic of iron deficiency anemia, when, in fact, no more than 10 percent of the population with these symptoms actually suffer from anemia, and that Geritol was suitable for treatment of all cases of anemia, when, in fact, medical attention is required in cases of severe anemia.[33]

The court reached back, beyond *Alberty* to the general principle, that even though each individual statement in an advertisement may be literally true, the overall impression created by that advertisement may not be false and misleading.

> The Commission, in looking at the overall impression created by the advertisements on the general public, could reasonably find these advertisements were false and misleading. The finding that the advertisements link common, non-specific symptoms with iron deficiency anemia, and thereby create a false impression because most people with these symptoms are not suffering from iron deficiency anemia, is both reasonable and supported by substantial evidence. The Commission is not bound to the literal meaning of the words, nor must the Commission take a random sample to determine the meaning and impact of the advertisements.[34]

The court distinguished *Alberty* on the grounds that the District of Columbia Court of Appeals had, in that case, held that the Federal Trade Commission must find that the failure to make an affirmative statement is misleading because of things claimed in the advertisement, and that the Federal Trade Commission had not made such a finding.[35] A finding, of this precise type, however, the Sixth Circuit continued, was the basis of the present order.[36] The court went on to point out

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[31] *Id.*, appendix, Table II.

[32] *Supra*, n. 10.

[33] *Id.*

[34] *Id.* at 889-890.

[35] Alberty, *supra* n. 26.

[36] *Id.*

that, in two cases subsequent to *Alberty*, the Second[37] and Fifth[38] Circuits had upheld similar orders based upon the same type of findings.

The court, however, did not require affirmative disclosure to the complete extent sought by the Federal Trade Commission.[39] While it enforced the Commission's order with respect to the points discussed above, it refused to enforce a portion of the order which forbade petitioner from representing or implying that iron deficiency anemia can be self-diagnosed or can be determined without a medical test.[40] Without citations, the court referred to a "Congressional policy in favor of self-help" and concluded that any such requirement was beyond the power of the Federal Trade Commission. For a short time, it appeared that this decision would mark the limits of the "affirmative disclosure" requirement. However, as we shall see, these boundaries have been extended by later cases.

The rationale of the *Williams* case received additional support by the Sixth Circuit in two pharmaceutical cases decided in 1968. While neither case involved the question of affirmative disclosure, both represent strong authority for the proposition that even though every statement in an advertisement may be technically true, if the overall impression created is deceptive, the advertisement is false and misleading. As we have seen, this concept is integral to the reasoning of the *Williams* case.

In the first of these,[41] the petitioner, Merck & Co., objected to a Federal Trade Commission order prohibiting it from advertising that "Sucret" Throat Lozenges would kill the Staph and Strep germs which are frequently associated with sore throats. Petitioner pointed out that extensive laboratory and clinical tests had conclusively established the efficacy of the active ingredient of the lozenges, hexylresorcinol, in killing these microorganisms. The court found, however, that:

> The evidence supports the following conclusions by the Commission: (1) that regardless of whether Sucrets can kill germs on the surface of the throat, they will not kill such bacteria in a manner that is medically significant; (2) that Sucrets cannot effectively attack (the) viruses which cause a viral sore throat; and (3) that Sucrets do not cure or help cure an existing sore throat infection.[42]

Further, streptococcal throat infections represent a particular hazard in that, untreated, these infections frequently lead to acute rheumatic

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[37] Ward Laboratories, Inc. v. F.T.C., 276 F. 2d 952 (2d Cir. 1960).

[38] Keele Hair and Scalp Specialists v. F.T.C., 275 F. 2d 18 (5th Cir. 1960).

[39] *Supra* n. 37, 38.

[40] *Id.*

[41] Doherty, Clifford, Steers & Sheffield, Inc. and Merck & Co. v. F.T.C., 392 F. 2d 921 (6th Cir. 1968).

[42] *Id.* at 926.

fever or nephritis. Thus, the court concluded, while the petitioner's product may kill staph and strep germs, to allow him to advertise that fact would allow him to create a misleading, and potentially dangerous, overall impression. The Commission's order was upheld in its entirety.[43]

The second case involve our old friend, Preparation-H.[44] The advertisement in question read:

> Doctors report a new healing medication . . . Preparation-H. . . actually shrinks hemorrhoids without surgery. Tests in famous hospitals and clinics reveal: Preparation-H relieves pain promptly—heals injured tissue. The secret? Only Preparation-H has the new wonder substance we call Bio-Dyne to draw the body's own healing oxygen to the painful area. Here are the dramatic results: One—Preparation-H relieves pain and itching promptly. Two—Preparation-H heals injured tissue. And three—Preparation-H shrinks hemorrhoids . . . even, in cases of twenty years' suffering . . . Preparation-H shrinks hemorrhoids without surgery!

Petitioner introduced evidence, at the Federal Trade Commission hearing, of a clinical study which showed that Preparation-H did, in fact, relieve the pain and itching associated with hemorrhoids and, in many cases, reduced the size of the affected area. Nine proctologists, specialists in diseases of the rectal area, testified before the Commission, however, that the only known permanent cure for hemorrhoids was surgical removal or ligation of the varicose veins which are the underlying cause of the ailment. Ointments or suppositories, such as Preparation-H, could only provide temporary relief of the symptoms associated with hemorrhoids. Further, the physicians testified, the astringent contained in Preparation-H, "Bio-Dyne," had no significant value in the treatment of the disease.[45]

The Commission found that the total impact of the advertisement was a false and misleading implication that Preparation-H would cure hemorrhoids. It issued a broad and complex order prohibiting petitioner from misrepresenting, directly or by implication, the efficacy of Preparation-H or any other drug.[46] The use of the word "Bio-Dyne," or any other word which implies the existence of a unique healing ingredient, was specifically prohibited.[47]

While the court found that the order, as written, was too broad in that it prohibited claims that Preparation-H would, in many cases, afford temporary relief from pain and itching and prohibited misrepresentations of other drugs not involved in the hearing, it upheld the

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[43] *Id.* at 929.

[44] American Home Products, Inc. v. F.T.C., 402 F. 2d 232 (6th Cir. 1968).

[45] *Id.* at 236.

[46] *Id.* at 237.

[47] *Id.*

major part of the Commission's order.[48] It remanded the order to the Commission for the removal of the overbroad parts, but issued an injunction *pendente lite* prohibiting the petitioner from disseminating any advertisements in connection with Preparation-H which "(1) represents, directly or by implication, that the use of such product will (a) avoid the need for surgery as a treatment for hemorrhoids or hemorrhoidal surgery, (b) heal, cure or remove hemorrhoids or eliminate the problem of hemorrhoids, or (2) contains any reference to the word 'Bio-Dyne.'"[49]

The limitations on the Federal Trade Commission's power to require affirmative disclosure, articulated in the *J. B. Williams* case, appear to have been removed in the Sixth Circuit's most recent opinion[50] in the area of over-the-counter pharmaceutical advertisements. Once again, a Federal Trade Commission order concerning a vitamin-mineral preparation for the treatment of "tiredness" symptoms was before the court. The order being considered was similar to that of the *J. B. Williams* case; it required affirmative disclosure of the facts that tiredness and lassitude are caused by many diseases other than iron deficiency and that SSS Tonic is effective only for the treatment of simple iron deficiency anemia. In addition, the order required affirmative disclosure of the fact that iron deficiency anemia cannot be self-diagnosed.

The radio advertisement in question read:

> Do you find yourself *missing out* on the fun of life? . . . Maybe you're suffering from Iron Deficiency Anemia—*low blood power.* If so, what you need is Three-S Tonic . . . rich in iron to help *build back* your blood power . . . *restore* your energy . . . help you *feel better fast!*

The court agreed with the Commission that the advertisement created the false impression that tiredness and lack of pep or energy were

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[48] *Id.* at 238.

[49] The end of the Preparation-H controversy is not yet in sight. On remand, the Federal Trade Commission redrafted its order to eliminate those portions which the court found to be too broad, but added a requirement of affirmative disclosure of the fact that, where Preparation-H reduces swelling, it is effective only where the swelling is "caused by edema, infection, or inflammation," thus ruling out a flat claim that the product will "help shrink hemorrhoids." Food, Drug and Cosmetic Reports ("The Pink Sheet"), p. 13, August 4, 1969. American Home Products, the manufacturer of Preparation-H has appealed the revised order. Food, Drug and Cosmetic Reports ("The Pink Sheet"), p. 12, December 1, 1969.

In a very recent case, Bristol-Myers, Inc. v. F.T.C., 424 F. 2d 934 (5th Cir. 1970), the Fifth Circuit has taken an almost identical stand regarding a similar FTC order involving advertising for Pazo, another hemorrhoid preparation. Judge Skelton, the author of the opinion, stated that he had found the Sixth Circuit's Preparation-H opinion to be of "great help" and that he had "borrowed extensively from it." Food, Drug and Cosmetics Reports ("The Pink Sheet"), p. 12, December 1, 1969.

[50] SSS Company, Inc. and Tucker Wayde & Company, Inc. v. F.T.C., 416 F. 2d 226 (6th Cir. 1969), Food, Drug and Cosmetic Reports ("The Pink Sheet"), Trade and Government Notes, p. 7, October 27, 1969.

the result of iron deficiency anemia, and would be cured by Three-S Tonic.[51] The truth, the court found, was that only a small minority of people suffer from these symptoms as a result of iron deficiency anemia, and in most cases, these symptoms are attributable to other causes which cannot be treated by Three-S Tonic. Further, the vitamins and herbs in the preparation are worthless in the treatment of iron deficiency anemia. The court found its decision in *J. B. Williams* controlling on these points and upheld this portion of the Commission's order.

The court reconsidered the "self-medication" limitation it had expressed in *J. B. Williams* and, relying heavily on Commissioner Elman's opinion, concluded that "self-medication" did not include "self-diagnosis." The distinction, the court said, between the two concepts had not been made by the Commission in the *J. B. Williams* case, nor had it been argued before the court.[52] While the court continued to recognize a strong Congressional policy in favor of self-help, this, the court said, cannot be considered to include self-diagnosis where sophisticated clinical tests are required to ascertain the existence of a disorder such as iron deficiency anemia.[53] "Regardless of the propriety of the application of the Congressional policy favoring self-help in *J. B. Williams Company,* we think it is inapplicable here. . . . In a case such as this, the fact that Congress may not have a policy against self-medication on a trial-and-error basis where the product is not harmful. . . cannot be used to sanction misleading advertising material." [54]

The petitioner argued that the Commission's order constituted a violation of its First Amendment right of free speech.[55] The court disposed of this argument without difficulty. "They are free to advertise their product; they are prohibited only from making false and misleading statements which they have no constitutional right to disseminate." The Sixth Circuit upheld the order in its entirety.

Recognizing the dangers of generalizing from a few cases in a single Circuit, I believe that *S.S.S. Corp. v. Federal Trade Commission* is indicative of the shape of things to come. Pharmaceutical advertising is to be held to a standard of absolute truthfulness. Not only must every statement made in those advertisements be literally and technically true, and not only must the total impact of the advertisement, when read by the audience towards whom it is directed, be true, but, where additional facts are required to properly evaluate the meaning of a statement in that advertising, affirmative disclosure of these facts will be required.

The Federal Trade Commission apparently agrees with this evalua-

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[51] *Id.* at 228.

[52] *Id.* at 229.

[53] *Id.* at 230.

[54] *Id.* at 230-31.

[55] *Id.* at 231.

ation. In their *Proposed Guides for Advertising Over-the-Counter Drugs*[56] the Commission has included the following tenative statement:

> An advertisement may be found to be deceptive not merely by what it says but by what it fails to say. . . An affirmative disclosure may be required in advertisements of over-the-counter drugs when it is necessary to prevent deception. In such cases, the disclosure should be clear and conspicuous . . . Affirmative disclosure will be permitted, as a substitute for an outright ban on an advertising claim found misleading or deceptive, only when disclosure will be fully effective in preventing deception and a more complete prohibition is unnecessary.[57]

The implication of the last sentence is particularly instructive. If a product cannot be advertised in such a manner as to avoid all possibility of deception, it may not be advertised at all!

The regulation of over-the-counter pharmaceutical advertising is in the vanguard of current regulatory developments. This is undoubtedly because of the highly technical nature of these advertisements, the inability of the lay public to accurately evaluate the validity of claims based upon scientific and medical facts, and the consequent potential for abuse and the danger to the public inherent in these advertisements. However, there is no reason to believe that the requirement of affirmative disclosure will be limited to pharmaceutical products. Already, a scattering of cases in other areas has upheld this requisite in other areas when special problems have been encountered.[58] I am convinced that the stringent requirement of absolute truthfulness, apparent in the most recent over-the-counter pharmaceutical cases, will ultimately become the *sine qua non* for all advertising.

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[56] 34 Fed. Reg. 5287, 21 CFR § 249 (Proposed); Cf., *supra* n. 14.

[57] 21 CFR § 249.2(a) and (d) (Proposed).

[58] *Cf.*, for example, Kerran v. F.T.C., *supra* n. 28, where the court affirmed an order by the Commission requiring affirmative disclosure of the fact that the oil sold to plaintiff was reprocessed used oil when there was no other way to distinguish it from new material, and Bantam Books, Inc. v. F.T.C., 275 F. 2d 680 (2nd Cir. 1960), where plaintiff was required to print the word "abridged" in "clear and conspicuous type" on the front cover of any abridged book it published.