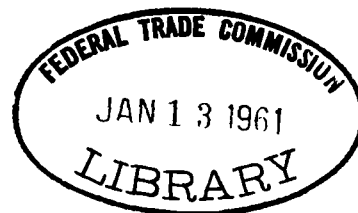


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CURRENT DRUG ADVERTISING



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Statement by Earl W. Kintner
Chairman, Federal Trade Commission
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I.

The Federal Trade Commission commenced its long effort to eradicate deceptive drug advertising soon after its organization some 46 years ago. Armed with the broad power to proscribe "unfair methods of competition in commerce" conferred by the Federal Trade Commission Act, the Commission soon determined that false and misleading advertising could inflict injury upon competition and thus was a subject of urgent Commission concern. The Commission issued a formal order proscribing deceptive advertising of a drug as early as 1918.^{1/}

This effort received major emphasis in the Commission's program in the years following, but in 1931 this effort was dealt a hard blow by the Supreme Court in the famous

1/ Block & Co., 1 F.T.C. 154 (1918).

Raladam case.^{2/} The Court held that the Commission could not proscribe false obesity cure advertising where no substantial competition, present or potential, was shown to have been injured or clearly threatened with substantial injury by the deceptive advertisement. A showing of actual injury to members of the consuming public, without more, was deemed to be insufficient to support the Commission's jurisdiction.

Precisely because this decision demonstrated that consumers were denuded of protection against harmful deceptive advertising, agitation soon developed for Congressional action to broaden the Commission's power in order that it might protect the consuming public as well as honest competitors. These efforts resulted in the passage of the Wheeler-Lea Amendments to the Federal Trade Commission Act in 1938. The basic prohibition of Section 5 now provides:

Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are hereby declared unlawful. ^{3/}

The primary purpose of the amendment to Section 5 of the Act was to counteract the Raladam decision, but the Wheeler-Lea Amendments were not limited to this purpose.

^{2/} Federal Trade Commission v. Raladam Co., 283 U.S. 643 (1931).

^{3/} 52 Stat. 111 (1938); 15 U.S.C. §45 (1958). Emphasis shows words added by amendment.

The 1938 amendments also added Section 12 to the Act,^{4/} declaring certain advertisements of foods, drugs, devices and cosmetics unfair or deceptive acts or practices in commerce within the meaning of Section 5, and armed the Commission with additional procedural weapons against the false advertising of these products that so closely affect the public health. Three distinct procedures and penalties were established in this area:

1. The Commission's cease and desist order procedures were strengthened. The Commission could continue to institute administrative proceedings looking toward an order to cease and desist. If no court review of the Commission's order is sought, it becomes final 60 days after its issuance. Violation of a final order subjects a respondent to a civil penalty of not more than \$5,000 for each violation. 5/

2. Criminal proceedings can be instituted where the advertisement is likely to induce purchase of one of the enumerated commodities which is either injurious to health or where there is an intent to defraud or mislead. Upon conviction the person disseminating such an advertisement is subject to a fine of not more than \$5,000 or imprisonment of not more than six months or both. 6/

3. The most significant weapon given to the Commission by the Wheeler-Lea Amendments is the right to secure a temporary injunction restraining the dissemination of a false advertisement of foods, drugs, devices or cosmetics pending the final determination of the Commission's administrative hearings and subsequent court review. 7/

4/ 52 Stat. 114 (1938); 15 U.S.C. §52 (1958).

5/ The finality provisions of the Wheeler-Lea Act apply to all orders issued under the Federal Trade Commission Act and are not limited to cases concerning foods, drugs, devices and cosmetics.

6/ 52 Stat. 115 (1938); 15 U.S.C. §54 (1958).

7/ 52 Stat. 115 (1938); 15 U.S.C. §53 (1958).

In addition to providing new enforcement weapons the Wheeler-Lea Act strengthened the Federal Trade Commission's effort against false food and drug advertising by including new jurisdictional and definitional concepts in Sections 12 and 15 of the Act. Section 12 provides that:

(a) It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement--

(1) By United States mails, or in commerce by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in commerce of food, drugs, devices, or cosmetics.

(b) The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in commerce within the meaning of Section 5. 8/

Under this section the Commission has jurisdiction whenever it appears that false advertisements of these four classes of products are disseminated (1) by United States mails, (2) in commerce by any means or (3) where there is a local dissemination of an advertisement which is likely to induce, directly or indirectly, a purchase in commerce. In one case an injunction was obtained involving a product that was dangerous to health on the mere dissemination of the advertisement, prior to any sale of the drug. ^{9/}

8/ 52 Stat. 114 (1938); 15 U.S.C. §52 (1958).

9/ Research Products Co., D. 3836.

Thus the broad jurisdictional concepts contained in Section 12 enable the Commission to act with great swiftness in appropriate cases.

Section 15 of the Federal Trade Commission Act,^{10/} added by the Wheeler-Lea Amendments, defines the term "false advertisement" in this manner:

The term "false advertisement" means an advertisement . . . which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representation or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual

Important lessons of general application can be gleaned from this definition. One lesson is that the law condemns the deceptive half truth as well as the outright falsehood. Another is that an advertisement may be deceptive even though every statement within it is literally true, because it fails to disclose material facts which are necessary for proper evaluation of the advertised product. Still another lesson is that an advertisement will be judged according to its total impression--a subtle qualification lost amid a welter of blatant puffing does not clothe an advertisement in the robes of legality.

^{10/} 52 Stat. 116 (1938); 15 U.S.C. §55 (1958).

These lessons are universal. They shape every element of advertising. The Federal Trade Commission has applied and extended these lessons in a host of decided cases. It would be both interesting and profitable to discuss a number of these cases with you. However, we are bounded by the strictures of time, and it may be more profitable to concentrate our attention on three areas, which, in my judgment, are of great current interest and importance to drug advertisers and are likely to increase in importance in the future. These areas are requirements for affirmative disclosure, the use of scientific test results to support claims of efficacy, and the use of claims of adequate quality control.

II.

In determining whether a drug advertisement is false, Section 15 of the Federal Trade Commission Act directs the Commission to consider not only direct falsehoods, but also failure to reveal material facts respecting consequences resulting from use of the product. It is under the authority of this provision that the Commission has required the inclusion of appropriate warning statements in advertisements for potentially harmful products.^{11/} The exercise of this power has engendered a considerable amount of controversy.

^{11/} Gelb v. Federal Trade Commission, 144 F.2d 580 (2d Cir. 1944); Aronberg v. Federal Trade Commission, 132 F.2d 165 (7th Cir. 1942).

In the Alberty case^{12/} the Commission considered the effect of an advertisement for a dietary supplement containing iron. The product was represented as being of value in the treatment of a number of vague symptoms, such as lassitude and fatigue. It was admitted that the product was of value in the treatment of these symptoms only in the case of iron deficiency and that the Commission could require any advertising claims be so restricted. In its order to cease and desist the Commission went a step further and attempted to require the disclosure that the symptoms in question were in fact due less frequently to iron deficiency than to other causes. Upon judicial review, Commission counsel argued that the order did no more than require the disclosure of a material fact within the intent of Section 15. The court held that this portion of the order was invalid, stating in part:

"The Commission must find either of two things before it can require the affirmative clause complained of: (1) that failure to make such statement is misleading because of the consequences from the use of the product, or (2) that failure to make such statement is misleading because of the things claimed in the advertisement. There is no such finding here." ^{13/}

Recent decisions of the Commission and the courts have clarified the power to require affirmative disclosure. These cases involved the advertising of treatments represented as

^{12/} Alberty v. Federal Trade Commission, 182 F.2d 36 (D.C. Cir. 1950).

^{13/} 182 F.2d at 39.

being of value in the prevention and cure of baldness. Within the past year the United States Courts of Appeals for the Second Circuit and the Fifth Circuit have affirmed orders of the Commission which limited claims for hair growth to cases other than those of male pattern baldness and required respondents' advertisements to clearly and conspicuously reveal the fact that the great majority of cases of thinning hair and baldness are the beginning and more fully developed stages of male pattern baldness, and that respondents' preparations will not in such cases check thinning hair, prevent or overcome baldness, cause new hair to grow, or cause hair to become thicker.^{14/} In the Keele decision the Court of Appeals for the Fifth Circuit stated:

"There is nothing in the Alberty case that prevents enforcement of a cease and desist order requiring affirmative disclosure. The Alberty case simply held that the Commission must make certain findings before compelling affirmative disclosure. The Commission made the required findings and on the basis of these findings issued its order requiring that the petitioners disclose affirmatively that Keele preparations would not be effective against male pattern baldness. Failure to disclose that approximately 95 percent of the cases of baldness fall within the male pattern type is plainly misleading, when the petitioners claim they treat virtually all cases of baldness."^{15/}

It would be reasonable to expect that the Commission will continue to insist upon affirmative disclosure in all instances where circumstances demonstrate that such

14/ Keele Hair and Scalp Specialists Inc. v. Federal Trade Commission, 275 F.2d 18 (5th Cir. 1960); Ward Laboratories Inc. v. Federal Trade Commission, 276 F.2d 952 (2d Cir. 1960).

15/ 275 F.2d at 21.

disclosure is necessary to protect the public. The Commission's recent use of informal industry-wide contact procedures to halt potentially dangerous practices through voluntary affirmative disclosures demonstrates its intensified activity in this area.

One recent example illustrates the efficacy of this technique. Letters from the Commission were sent to all known primary producers of drug products requiring them to include in their advertisements of drugs to be used on milk cows and other dairy animals, a conspicuous warning of how long the animals' milk must be withheld from human consumption after the drug is administered.

Heretofore, when antibiotics, such as penicillin, were sold for use in treating animals the drug labeling alone carried the warning. The warning usually was not carried in the drug advertisement. The Commission has not only rendered this practice unlawful but has also broadened the advertising requirements to cover not only antibiotics but all other drugs which might leave a residue in milk. Responses received to date have been gratifying. The alert was carried out with no fanfare because of a desire to avoid creating needless public concern. Confronted with an industry-wide problem, the Commission felt that no good purpose would be served by a piece-meal approach and therefore we used the same broad scale method of attack which

worked so successfully in the deceptive advertising of battery guarantees, tar and nicotine claims for cigarettes and deceptive tire advertising.

It is interesting to note that in complying with the request of the Commission for information, a number of firms engaged in the manufacture of animal antibiotics had not understood that catalogues and price lists are usually advertising subject to scrutiny by the Federal Trade Commission in the same general manner as direct mail solicitations, advertisements in newspapers and journals and radio and television commercials.

One exemption from the coverage of the Wheeler-Lea Amendments has been questioned with increasing frequency recently. The questioned exception provides that "No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representations of a material fact, and includes, or is accompanied in each instance by truthful disclosure of the formula showing quantitatively each ingredient of such drug."^{16/} Those who question the current validity and viability of this exception point out that there have been revolutions in pharmacology, immunology, biochemistry and the other life sciences since this exception was enacted in 1938. The geometric rate of medical discovery

16/ 52 Stat. 116 (1938); 15 U.S.C. §55 (1958).

coupled with increasing demands upon the time of medical practitioners now render it improbable that the average practitioner can immediately predict the efficacy, potency, contraindications and possible side-effects of a drug from a mere inspection of its formula. Therefore, the questioners say that since the assumptions upon which the exception is based are no longer valid, the exception must be modified or eliminated to protect the medical profession and the public which it serves. This questioning has not gone unheeded. It may interest you to know that members of the staff of the Federal Trade Commission have been giving serious thought to a draft revision of the Section 15 exception. However, it should be noted that the Commission itself has not as yet taken a position on this question.

III.

Nothing so animates a nation of science worshippers as the straight-forward claim that "independent laboratory tests prove" Claims of this character or visual demonstrations of "scientific facts" in a laboratory setting conducted by men clothed in laboratory garb can produce startling results at the sales counter. Because consumers are often convinced by "proof" of this character the Federal Trade Commission and the advertiser have important responsibilities in insuring that scientific tests used to support advertising claims actually prove what they are

alleged to prove and that scientific demonstrations actually demonstrate what they allege to demonstrate.

Advertisers who cite scientific tests in support of advertising claims must be prepared to show that these claims are backed by accurate and objective scientific findings. In the atmosphere of disenchantment that so recently surrounded the world of advertising, much talk was heard to the effect that one of the basic elements of trickery in advertising was due to the habit of consulting scientists in producing the result that the client desired, not the result that empirical proof and logic dictated. I think it fair to say that blanket allegations of this character have not been proven. The Federal Trade Commission has uncovered numerous instances of trickery in testing and undoubtedly it will continue to do so. But it does not condemn out-of-hand all testing conducted by and for advertisers. The Commission approaches scientific test results to support scientific claims without preconceived bias. However, in appropriate instances it rigorously checks all aspects of such tests to evaluate the advertising claims.

When our attention has been focused on an advertising claim supported by scientific tests we commence our investigation by examining the raw data supporting the laboratory reports. In the course of this examination we employ a set of universal criteria regardless of the nature of the test examined. These are the questions that we ask:

- (1) Has the experiment been properly designed?
- (2) Has the experiment been performed correctly?
- (3) Have a significant number of tests been conducted?
- (4) Have the test results been recorded accurately?
Are the results internally consistent and coherent?
- (5) Do the test results warrant the conclusions drawn?
- (6) Can the conclusion be expressed in a meaningful,
accurate way to consumers who lack scientific
training?

Note that these questions examine the employment of both scientific and communication skills. Neither the advertiser nor the advertising agency nor the scientist is immune from responsibility for the scientific claim. Both the public interest and enlightened self-interest dictate that all who contribute to the preparation of an advertisement based upon scientific tests insure that no taint of implicit or explicit deception mars the advertisement.

IV.

The Federal Trade Commission polices only the advertising of drug products. It has no power to regulate the development or production of drugs. Therefore, when I speak of Federal Trade Commission actions and positions in the area of quality control it must be clearly understood that my remarks are limited to claims of effective quality control made in advertisements.

Most Commission cases challenging advertising statements as false and misleading have been directed at statements concerning the attributes of the products advertised. However, the activities or processes of a firm can also be misrepresented and an advertiser is fully liable for representations of this character. This principle is illustrated by advertisements which state or imply without foundation that the firm exercises adequate quality control over the manufacture of its products. The specific term employed may be "a system of quality control", "rigid quality control" or a host of others, but the uniform implication is that a careful check on the quality of the manufactured product is maintained. It is the duty of the Federal Trade Commission to insure that statements of this character accurately reflect the nature of the manufacturer's operation. This oversight is particularly important in the manufacture of pharmaceuticals.

The Commission's position is that any advertising claim relating to quality control is a representation, within the accepted meaning of the terms as understood in the pharmaceutical industry, that the firm employs an adequate control system.

Obviously any examination of the truthfulness of a claim of adequate quality control must depend upon a careful and useful definition of the phrase "adequate quality control."

To assist your thinking in this area I will repeat for your consideration a definition devised by Mr. Thomas Riggs of the Commission's Division of Scientific Opinions. This definition has not been adopted or considered by the Commission, but it can serve as a useful touchstone in your thinking on this subject. This is the definition:

An adequate control system observes the regular and continuous use of all reasonable methods, procedures and operations that are necessary, and sufficient to insure the uniformity of pharmaceutical products as to safety and efficacy, including the use of those which will:

- (1) minimize the human, mechanical and other errors throughout all phases of production such as manufacturing, processing, packaging and labeling, and
- (2) assure the user or ultimate consumer that his package of the product has all the characteristics of identity, strength, quality, and purity which it is represented or purported to possess, including those which are required, claimed, or implied, taking into account each of the uses for the product which are intended, represented or customary.

This definition encompasses a wide ranging concept of adequate quality control. No mere plan for control will satisfy the definition. In order to insure adequate control the manufacturer must have not only a plan but also the facilities and procedures, the qualified staff and the know-how necessary to carry out the program on a continuous basis. Close inspection at the point of manufacture is necessary to check the claim of adequacy.

The Federal Trade Commission must bear special responsibilities in the area of quality control for, insofar as standard pharmaceuticals are concerned, it is the sole agency empowered to protect the public. The Commission's responsibility is particularly heavy at this time because of the recent expanded use of generic-name drugs and the concomitant use of claims of adequate quality control by the manufacturers of such drugs. The public must necessarily be vitally concerned with the quality of pharmaceuticals, and governmental agencies charged with the protection of the public interest must necessarily reflect that concern. Public awareness of false claims of quality control can severely damage the reputations of the pharmaceutical industry and can invite massive governmental controls. Therefore, it behooves the industry, acting in the public interest and enlightened self-interest, to cooperate with the Federal Trade Commission in insuring that all claims of adequate quality control are truthful. Inattention and callousness in this area invite disaster.

Unfortunately, for many years the Commission had done very little to police claims of quality control. However, in the past year the Commission has moved with vigor in this area. Evidence of this vigor may be found in the issuance of a formal complaint against a manufacturer of generic-name drugs last October. The Commission is now investigating a

number of claims of quality control made by manufacturers of all types of pharmaceuticals. You may be sure that if these investigations engender reason to believe that deceptive claims of quality control have been made, corrective action will soon be forthcoming.

V.

Today we have examined only three of the many sensitive areas of drug advertising. Attention could profitably be devoted to a host of other specific points, but the precept that must guide you continuously is already clear. The operative principle is that every drug advertisement must scrupulously adhere to the truth. It must be truthful in its negations as well as in its declarations. It must avoid misleading implications just as it must avoid explicit falsehoods. Its truth must be as capable of perception by the credulous as it is by the sophisticated. The advertisement must be true. It must be true in all its aspects.

The reputation of drug advertising is a trust of every advertiser and every advertising agency connected with the industry. By faithfully discharging that trust you can furnish a shining example of your industry's concern for the public interest. If you fail to discharge that trust you must be prepared to accept massive governmental control, for the abdication of self-discipline always invites imposed discipline.

Aware consumers and honest competitors will not long tolerate the trampling of truth in the pursuit of avarice. It would be the height of irony for the advertising industry to "wince and cry aloud" at tighter government controls if it has amply demonstrated that it recognizes no other controls.

The enjoyment of freedom depends upon the discharge of responsibility. If you wish to remain a free industry subject only to limited legal controls then there is no better time than the present to demonstrate that your industry deserves to be free.

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