

CTFA

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

October 28, 2002

E. EDWARD KAVANAUGH
P R E S I D E N T

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857

Re: Docket Number 02N-0209

Dear Sir or Madam:

These comments are filed by The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA") to supplement our principal comments of September 13, 2002 in response to the Food and Drug Administration's (FDA's) "Request for Comment on First Amendment Issues."¹ This additional comment is filed in response to the numerous comments filed by a wide range of groups, companies and individuals as of that date.

We believe the comments filed on or before September 13 indicate broad support for the need to reevaluate the manner in which FDA restricts speech about regulated products and to ensure that the Agency's analysis of proposed regulations affecting commercial speech follows that required in Thompson v. Western States Medical Center, 122 S. Ct. 1497 (2002) (hereafter "Western States").

CTFA and many other parties have consistently and carefully articulated the analysis that must be performed before any government curtailment of speech can occur. We believe the comments filed to date reflect an overwhelming consensus supporting the development of guidelines for such a First Amendment analysis that must be followed consistently throughout the Agency. It is important that the Agency conclude this process by publishing those guidelines for public comment after consideration of the additional comments filed on the October 28 deadline.

Some interested parties have stated a concern that a review by FDA of its First Amendment compliance will, by definition, result in less protection of the public health. That is by no means the case. A better informed consumer armed with

¹ 95 Fed. Reg. 34942 (May 16, 2002)

02N-0209

C94

more – not less – truthful information is much more likely to use FDA-regulated products in a way that insures both safety and the maximum possible benefit from the product.

In addition, the First Amendment analysis required by the Central Hudson² and Western States opinions fully allows for FDA to make decisions that are necessary to protect the public health and safety. In fact, the analysis dictated by the U. S. Supreme Court calls for consideration of whether the government interest is substantial and whether the regulation directly advances the government interest asserted.

In Western States, the Court recognized FDA's interest in preserving the integrity of the drug approval process. However, the Court then found that – even assuming the ban on advertising furthered the interest of preserving the approval process – the ban on advertising and solicitation for compounded drugs went too far in restricting speech and was therefore unconstitutional. In reaching that conclusion, the Court took the unusual step of reviewing possible actions FDA could take to further its interests without restricting speech.

Compliance with the Constitutional mandate to protect freedom of speech and the consumer's right to have relevant information regarding FDA-regulated products is not discretionary for the Agency. It should always have been part of FDA's past deliberations, and certainly must be part of its future consideration of restrictions of speech under Western States.

The First Amendment clearly does not allow for government censorship of truthful and relevant information about products, even when that censorship may be motivated by good intentions. The Supreme Court was clear in Western States in stating that

“If the First Amendment means anything, regulating speech must be a last – not first – resort.”

The actions that CTFA recommended in our September 13 comment are designed to achieve appropriate consideration of both the consumer's right to have truthful and relevant information about the cosmetic and OTC drug products they purchase and protection of the public health and safety. These proposals are also supported by the comments of others.

CTFA recommended that FDA provide greater flexibility for manufacturers to provide information to consumers regarding drugs subject to the OTC drug monograph process. Similar concerns were expressed by the Consumer

² Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980).

Healthcare Products Association.³ Despite efforts by FDA to provide some limited flexibility under the monographs, the OTC drug monograph process is still implemented and enforced under a “command and control” regulatory approach.

The current FDA approach to regulation fails to comply with the analysis required by Western States in two important respects. First, the Agency often fails to require sufficient justification when it requires the use of very specific language for certain claims. Second, by denying flexibility in how the manufacturer communicates to the consumer, the Agency effectively bans alternate means for communicating truthful and non-misleading information to that consumer.

Specific examples of Agency decisions that must be corrected to comply with First Amendment requirements were cited in our September 13 comment:

1. FDA must reconsider and change its decision banning high SPF claims for sunscreens, limiting anti-aging claims to an agency-prescribed “sun alert” statement, and severely restricting the uses and directions that are permitted for sunscreens.
2. FDA must reconsider the totally inflexible approach to labeling required by the OTC Drug Labeling Regulation.⁴ This rule prevents truthful information from being communicated on the label. By not allowing less restrictive ways to achieve the same goals such as reduced labeling for cosmetic drugs and small package exemptions for appropriate OTC drug products, it will have the effect of eliminating certain forms of the products from the marketplace.

In this regulatory environment, FDA must measure whether a claim is “inherently deceptive” according to the reasonable consumer standard currently applied by the Federal Trade Commission instead of banning speech simply because a claim may be misunderstood by an “ignorant”, “unthinking” or “credulous” consumer. CTFA’s initial comment stressed the importance of FDA updating its approach to measuring whether claims are deceptive to take into account the FTC’s Policy Statement on Deception which states that

“An advertiser cannot be charged with liability with respect to every conceivable misconception, however outlandish, to which his representations might be subject among the foolish or feeble-minded.

³ Comments of the Consumer Healthcare Products Association, September 13, 2002, at pp. 3-5.

⁴ Also see Comments by the Consumer Healthcare Products Association, September 13, 2002, at p. 5.

Some people, because of ignorance or incomprehension, may be misled by even a scrupulously honest claim.”⁵

The Federal Trade Commission itself has stressed many of the same points in addressing the First Amendment issues facing FDA. Citing the Policy Statement on Deception, the FTC states that

“The meaning of the ad and the likelihood of deception is considered from the perspective of a reasonable member of the audience to whom the ad is directed. What constitutes deception may be different, for example, for advertising aimed at the terminally ill, a group that might be particularly vulnerable to exaggerated cure claims, than it would be for advertising aimed at health professionals whose experience has given them expertise in the advertised products.”⁶

CTFA believes that FDA oversteps the limits of the First Amendment when it determines that the consumers of everyday personal care products such as sunscreens and antiperspirants have to be protected from truthful information about the benefits of these products.

FDA has improperly banned the communication of truthful information about these products on the remote chance that a few may not be able to comprehend the meaning of those claims and may misuse the products. However, the risk of product misuse is low, the possibility of misunderstanding is remote, and the costs – in some cases health risks - of keeping truthful information about these products from reasonable consumers are very high.⁷

We do not suggest that FDA should take its public health responsibilities any less seriously. However, we strongly urge FDA to give substantial weight to the expertise and experience of its sister Agency charged with the responsibility of evaluating advertising claims for many of the same products regulated by FDA. This analysis calls for evaluating truthful claims in labeling in light of the real-world reasonable consumer shopping for personal care products in a real life supermarket, drug store, or other OTC drug outlet.

⁵ Federal Trade Commission Deception Policy Statement, appended to *Cliffdale Associates, Inc.* 103 F.T.C. 110 (1984)

⁶ Comments of the Staff of the Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission, September 13, 2002, at p.15; Also see Comments of the Grocery Manufacturers of America, September 10, 2002, at pp. 5-8.

⁷ For example, medical authorities widely agree that truthful information about the availability of high SPF sunscreens enables consumers to obtain protection against skin cancer and other forms of sun damage to the skin.

Dockets Management Branch
October 28, 2002
Page 5

We again appreciate the opportunity to discuss these issues with the Agency, and would be pleased to answer questions or provide additional information as needed.

Respectfully submitted,

A handwritten signature in black ink that reads "Edward J. Kavanaugh". The signature is written in a cursive style with a large, prominent loop at the end of the last name. A diagonal line is drawn across the signature from the top left to the bottom right.

E. Edward Kavanaugh
President