Docket No. 94P-0036

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

Concerning

FOOD LABELING: TRANS FATTY ACIDS IN NUTRITION LABELING, NUTRIENT CONTENT CLAIMS, AND HEALTH CLAIMS

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March 27, 2003

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Via email and U.S. Mail
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims -- Proposed Footnote Statement Docket No. 94P-0036; 67 Fed. Reg. 69171 (November 15, 2002)**

Dear Sir or Madam:

The Washington Legal Foundation (WLF) submits these comments in response to the Food and Drug Administration's (FDA) proposed rule regarding food labeling with respect to trans fatty acids (trans fats). In particular, WLF is commenting on FDA's proposal (first released in the November 15, 2002 Federal Register) to require a footnote statement when trans fat is listed on a food label. The footnote would state, "Intake of *trans* fat should be as low as possible."

WLF strongly opposes adoption of such a footnote requirement. The First Amendment prohibits imposition of the requirement because speakers cannot (except in very limited circumstances) be required to speak against their will, and food manufacturers are virtually unanimous in objecting to the proposed footnote because they deem it misleading. Although the First Amendment permits the government to compel commercial speech when necessary to prevent consumers from being confused or deceived, there is no serious argument that the footnote statement is necessary to prevent food labels from being confusing or deceptive. While the proposed footnote statement may constitute sound health information, it is not the

role of the government to commandeer the property of others for the purpose of spreading information that may promote public health. If the government wishes to spread information regarding potential risks from overconsumption of trans fat, it should do so on its own nickel.

Interests of WLF.

WLF is a public interest law and policy center with supporters in all 50 states. While WLF engages in litigation and administrative proceedings in a variety of areas, WLF devotes a substantial portion of its resources to promoting the interests of a free-market economy and to defending the rights of individuals and businesses to go about their affairs without undue interference from government regulators. For example, WLF recently successfully challenged the constitutionality of FDA restrictions on commercial speech regarding off-label uses of FDA-approved products. *Washington Legal Foundation v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000). WLF has participated in many of the leading U.S. Supreme Court cases regarding the scope of commercial speech rights. *See, e.g., 44 Liquormart, Inc. v. Rhode Island,* 517 U.S. 484 (1996). WLF has regularly participated in rulemaking proceedings before federal agencies on regulatory matters relating to food advertising/labeling. *See, e.g., Comments of WLF on Voluntary Labeling Indicating Whether Foods Have or Have not Been Developed Using Bioengineering* (March 19, 2001); *Comments of WLF on USDA's Proposed Rule on National Organic Program* (June 12, 2000); *WLF Comments in Response to Petition of Center for Science in the Public Interest to*

Federal Trade Commission Regarding Advertisements for Olestra and Olestra-Containing Products (September 28, 1998). WLF's Legal Studies Division has published numerous studies and policy papers regarding the permissible scope of government regulation of commercial speech. *See, e.g.*, Christopher A. Brown, *FDA Trans Fat Label Rule Violates the First Amendment*, WLF COUNSEL'S ADVISORY (publication forthcoming).

FDA's Proposed Footnote Statement.

The Nutrition Labeling and Education Act of 1990 ("NLEA"), Pub.L. 101-535, authorizes FDA to require that certain nutrient information be included on food labeling. In particular, the NLEA authorizes FDA to supplement the list of nutrients that the statute explicitly requires be included on food labels if it finds that such action is necessary to assist consumers in maintaining healthy dietary practices. *See* 21 U.S.C. § 343(q). Pursuant to that authority, FDA in November 1999 proposed an amendment to its nutrition labeling regulations to require that the amount of trans fat present in a food in the amount and percent Daily Value ("% DV") declared for saturated fatty acids.

Before a final regulation could be issued, a report from the Institute of Medicine of the National Academy of Sciences ("IOM/NAS") concluded: (1) increased trans fat consumption is associated with increased risk of coronary heart disease; (2) reduced levels of trans fat consumption are good for one's health; and (3) it is unrealistic and unwise to recommend an end to all trans fat consumption because trans fats are unavoidable in ordinary diets and the

major overhaul of dietary habits necessary to avoid all trans fats could pose unknown health risks. As a result of the IOM/NAS report and other research, the consensus of dietary professionals is that consumers should seek to limit trans fat in their diets.

In its November 15, 2002 Federal Register notice, FDA points out that the IOM/NAS report does not provide a dietary reference intake figure for trans fat. FDA contends that in the absence of any information from IOM/NAS from which FDA could compute an acceptable daily intake of trans fat, it cannot compute a daily reference value -- from which % DV information for trans fat could in turn be derived. Accordingly, FDA proposes requiring that an asterisk be placed in the % DV column for trans fat when it is listed. It proposes that the asterisk be tied to another asterisk at the bottom of the Nutrition Facts box, to be followed by the statement, "Intake of *trans* fat should be as low as possible." FDA contends that such a statement is necessary to comply with the NLEA, which authorizes FDA to adopt regulations requiring label information regarding nutrients (such as trans fat) not mentioned in the NLEA "for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices." 21 U.S.C. § 343(q)((2)(A).[1] FDA

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[1] As additional authority for requiring the footnote statement, FDA cites § 2(b)(1)(A) of the FLEA, 21 U.S.C. § 343 *note*, which states that certain regulations issued by FDA under the FLEA should require the declaration of nutrients to "be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of *a total daily diet*." (Emphasis added.) FDA's reliance on the "a total daily diet" language is misplaced. FLEA § 2(b)(1)(a) relates solely to FDA regulations adopted within 12 months of enactment of the FLEA. Section

apparently contends that consumers will not be assisted in "maintaining healthy dietary practices" with respect to trans fat consumption in the absence of either a % DV value or a footnote along the lines proposed by FDA. The Federal Register notice includes nothing to indicate that FDA has considered the First Amendment ramifications of requiring the proposed footnote.

First Amendment Limitations on Compelled Speech.

The First Amendment's protection against any law "abridging the freedom of speech" includes the right not to speak. *See, e.g., West Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943) (State may not compel students to recite the Pledge of Allegiance); *Wooley v. Maynard,* 430 U.S. 705 (1977) (State may not compel drivers to display the slogan "Live Free or Die" on automobile license plates). Although the government may sometimes impose restrictions on truthful *commercial* speech if its asserted interests are sufficiently strong, *see Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n,* 447 U.S.. 557 (1980), the rationale justifying *restrictions* on commercial speech would not seem to support *requiring* companies to engage in commercial speech against their will, except in very limited circumstances. The government may require commercial speakers to include disclaimers in their speech in order to "dissipate the possibility of consumer confusion or deception."

2(b)(1)(a) reference to "a total daily diet" is not repeated in sections of the FLEA that *are* directly applicable to regulations -- such as FDA's proposed trans fat regulation -- adopted pursuant to 21 U.S.C. § 343(q)(2)(A).

Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985). Under *Zauderer,* ingredient labeling requirements are permissible when they provide material information to consumers and thus "dissipate the possibility of consumer confusion or deception." But there can be no First Amendment warrant for a regulation compelling companies to speak against their will, in the absence of such a showing. Thus, in determining the constitutionality of FDA's proposed footnote statement, the relevant question is whether the statement "dissipate[s] the possibility of consumer confusion or deception."

The Value of Food Labeling Requirements.

The NLEA clearly passes constitutional muster under the *Zauderer* test. Consumers have a strong interest in knowing what nutrients are contained in the food they are eating. While consumers can determine on their own the nutrients contained in raw foods (*e.g.,* fresh fruits and vegetables), they have no ready means of determining what nutrients are contained in processed foods. It would be wholly unrealistic to expect consumers, before eating processed foods, to engage in laboratory testing of each food item they purchase. Yet, in the absence of either home testing or product labeling, consumers are highly likely to be confused regarding the nutritional content of processed food. Accordingly, Congress did not violate the First Amendment when it required processed food manufacturers to list on the product label the quantity of designated nutrients contained in the product.

FDA has extended the statutory requirement to mandate inclusion of the "% DV" for

each listed nutrient. WLF does not doubt that in doing so, FDA was acting within its statutory authority. FDA's constitutional authority for doing so is somewhat less clear, given that a consumer who has been accurately informed regarding the quantity of the nutrients in the food he has purchased is unlikely to be either "confus[ed]" or "dece[ived]" regarding the nutritional content of that food -- even in the absence of "% DV" information. On the other hand, the "% DV" for a given nutrient is information that most consumers appreciate because it provides *significant* assistance in better understanding the nutritional quantity information. Moreover, at least in those instances in which the "% DV" calculation is not subject to dispute, manufacturers are unlikely to object strenuously to being forced to include this information.

The Footnote Statement Violates the First Amendment.

Based on the IOM/NAS study, FDA has concluded that it is unable to calculate a daily reference value for trans fat -- and thus is unable to calculate a "% DV" for foods containing trans fat. That conclusion obviously would justify an FDA decision to mandate that the "% DV" column for trans fat be left blank on product labels. For products labeled in that manner, consumers would know precisely how much trans fat is contained in the products and would also be placed on notice that, for whatever reason, trans fat (uniquely among listed nutrients) has no "% DV" information. Consumers who pay attention to nutrient labeling information and are unaware of the health risks of excessive trans fat consumption would thus be prompted to investigate further.

But the proposed footnote statement goes much further than that. It warns ominously, "Intake of *trans* fat should be as low as possible." Many consumers would conclude from such a statement that they should avoid altogether consumption of any food containing trans fat. As FDA well knows, any such conclusion would be wholly unwarranted. Indeed, the Federal Register Notice concedes, "[*T*]*rans* fats are unavoidable in ordinary diets, and achieving [zero intake] would require extraordinary changes in dietary intake patterns that might introduce other undesirable effects and unknown health risks." Moreover, the proposed footnote statement does not distinguish among foods based on the level of trans fat; *all* foods containing any amount of trans fat would contain the same footnote statement. Consumers could thus be misled by the footnote statement into believing that the health risks of food containing a high level of trans fat are identical to the health risks of food containing a low level of trans fat.

While inclusion of the footnote statement could well cause confusion and deception, exclusion of such a statement almost surely would not. Even without the footnote statement, consumers will be able to determine precisely how much trans fat is contained in a product they have purchased, and they will be on notice that they have not been provided with a "% DV" figure for that quantity of trans fat. Mandated warning labels can, of course, be constitutionally permissible in extreme circumstances where *any* consumption of the product is known to have adverse health effects. For example, warning labels on cigarette labels pass constitutional muster because it has been determined by the Surgeon General that any amount

of smoking is bad for health. But the most that can be said in this instance is that medical authorities have not determined that consumption of small amounts of trans fat is *not* bad for one's health. Under those circumstances, it cannot be said that a label that fails to comment on optimal daily trans fat intake is either confusing or deceptive. Accordingly, the First Amendment does not permit FDA to mandate inclusion of the footnote statement on product labels -- particularly given that the statement proposed by FDA is itself likely to mislead consumers.

Requiring inclusion of the footnote statement is particularly inappropriate in light of Congress's failure to include any language in the FLEA to suggest that such statements are mandated. Congress has done no more than to *authorize* FDA to require such labeling as FDA deems necessary to "assist consumers in maintaining healthy dietary practices." 21 U.S.C. § 343(q)((2)(A). Contrary to FDA's contention in the Federal Register notice, Congress has never indicated that regulations of the type that FDA is contemplating here *must* include information about daily intake of specified nutrients. Accordingly, in attempting to restrict speech rights in this instance by compelling manufacturers to speak against their will, FDA cannot pass the blame to Congress; any such restrictions are of FDA's own doing. In the absence of evidence that this significant infringement on speech rights is necessary to prevent consumer confusion or deception, the First Amendment prohibits FDA from mandating inclusion of the footnote statement on product labels.

CONCLUSION

The Washington Legal Foundation respectfully requests that the FDA not mandate inclusion of its proposed footnote statement on the nutrition labels of products containing trans fat.

Respectfully submitted,

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