

cholesterol, to incorporate nutrition education information about recommended contributions for all three fats to the diet when making healthier food choices. There is ample discussion in section IV of this document about the heart unhealthy effects of consuming *trans* fat and there is a new and strong consensus among the scientific community for reducing *trans* fat intake. Thus, the agency believes it is within the bounds of its statutory authority under section 403(q)(2)(A) of the act to require the listing of *trans* fat on the food label, which listing is not dependent on the presence of claims or other voluntary fat information.

B. The First Amendment

Several general comments were received asserting that the agency's action to mandate labeling is subject to review under the first amendment. The comments assert that mandatory labeling of *trans* fat is commercial speech, and thus, such speech is entitled to the full range of first amendment protections as all commercial speech (citing to *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)). The comments further assert that "compelled speech" is entitled to the same protections as speech "bans," (citing to *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 477 U.S. 557 at 566 (1980)). One comment explained that the court in *Pearson* emphasized that the first amendment does not allow FDA to restrict truthful, nonmisleading information as a "paternalistic" means of directing consumer food choices (164 F.3d at 656 (citing *Bates v. State Bar of Arizona*, 433 U.S. 350 at 377(1977) ("[W]e view as dubious any justification that is based on the benefits of public ignorance.")); 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (opinion of Stevens, J. joined by Kennedy, J., and Ginsburg, J.) ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.")). The comment further cited several cases for the proposition that the government cannot compel speech when disclosures are not necessary to materially alleviate real consumer harm (citing to *IDFA v. Amestoy*, 92 F.3d 67, 73 (2nd Cir. 1996); *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136 (1994); and *Edenfield v. Fane*, 507 U.S. 761 (1993)). Another comment suggests that the agency needed to consider the limitations imposed by the first amendment to avoid unjustified burdens and costs on food labeling where there is no genuine

public health benefit from a rule that does not materially alleviate a genuine harm of potential consumer deception.

Some comments assert that FDA's proposal to mandate *trans* fat labeling does not remedy a concrete harm as required by the first amendment. One comment suggests that a *trans* fat labeling rule could be supported if carefully crafted to remedy consumer deception but not where risk of consumer deception cannot be established as a genuine harm. Other comments state that FDA did not tailor its approach to labeling and would be requiring mandatory labeling of *trans* fat for foods containing as little as 0.5 g *trans* fat, which would not alleviate a genuine harm. The comment seems to further suggest that including *trans* fat in the total fat content on the label would be sufficiently tailored to alleviate a genuine harm. Another comment states that there is mere speculation in the record that providing information on *trans* fat would assist consumers to maintain healthy dietary practices, and thus, is not narrowly tailored to materially alleviate a genuine harm.

A few comments state that treating *trans* fats the same as saturated fat on labeling would be the same as proposing to require false information on labels. Such an outcome, the comments state, would be indefensible on Constitutional grounds. One comment states that mandatory declaration of *trans* fat can only be justified under constitutional provisions when the absence of such declaration would constitute an omission of a material fact.

FDA believes that this regulation is consistent with the first amendment. As noted previously, the failure to disclose the amount of *trans* fat in a product is an omission of material fact. When a manufacturer makes explicit or implicit health claims, the failure to provide *trans* fat information is likely to mislead the consumer. Moreover, the reasonable consumer would expect that the information on the label would give them the most important nutrition information relative to the healthfulness of a product. Yet the omission of *trans* fat runs counter to that expectation, impeding rational consumer choice. As the agency has explained earlier, consumers need information about *trans* fat on all foods, not just those that contain a certain threshold level of *trans* fat, to reduce overall intake of *trans* fat in the diet. Consumers can use that information to compare products and make selections that can reduce their risk of CHD.

Accordingly, FDA believes that this final rule passes muster under the four-

part test in *Central Hudson* primarily because, as discussed previously, requiring the factual information on the amount of *trans* fat in labeling ensures that the label is not false or misleading. Under the first prong of *Central Hudson*, commercial speech must be related to lawful activity and not be misleading. Speech that is false or misleading is not protected and may be prohibited (*Central Hudson*, 447 U.S. 557 at 563–564).²

Given this determination, arguably the agency need not address the other three parts of the *Central Hudson* test at all. Nonetheless, and particularly in light of FDA's showing that such information is important to ensuring that consumers are adequately informed about the products they are buying, the proposed requirement satisfies the next three prongs. Turning to the second prong, the asserted governmental interest must be substantial. FDA's interest is clearly substantial, for at least two reasons. As noted previously, the FDA has a substantial interest in protecting and promoting public health and in preventing consumer deception by ensuring the accuracy and completeness of *trans* fat information in labeling. (See *Pearson*, 164 F.3d at 656.) The food labeling regulations seek to ensure that consumers have access to information about food that is scientifically valid, truthful, reliable, and not misleading. (58 Fed. Reg. 2478, 2526 (1993)). Consumers have a first amendment interest in obtaining information on which to base a decision, particularly one that has health consequences, regarding whether to buy a product, and this interest is "served by insuring that the information is not false or deceptive." (*National Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 162 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978)).

Moreover, FDA has a substantial governmental interest in assisting consumers to maintain healthy dietary practices. Such interest is consistent with the purpose of section 403(q)(2)(A) of the act; to provide information to consumers on nutrients (*trans* fat content of food) when such information is of public health importance. The government is not confined to asserting a substantial government interest in preventing consumer deception for a regulation before that regulation can sustain a first amendment review (*Rubin v. Coors Brewing Co.*, 514 U.S. 476, 484–

² The agency does not need to address the comments that asserted that proposing to treat *trans* fat the same as saturated fat in the November 1999 proposal would be the same as requiring false labeling. Since the agency is requiring separate line labeling in this final rule, those comments are moot.