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September 13, 2002

Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Request for Comment on First Amendment Issues
Docket No. 02N-0209
67 Fed. Reg. 34942 (May 16, 2002)

Dear Sir or Madam:

Enclosed please find comments by AARP in response to the May 16, 2002 Notice on First Amendment Issues.

Sincerely,

David Certner
Director
Federal Affairs

Enclosure

02N-0209

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
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I Introduction

AARP appreciates this opportunity to present its views regarding the impact of recent court cases involving the First Amendment on the authority of the Food and Drug Administration (FDA) to regulate the information that appears on product labels and in advertisements.

FDA regulates a wide range of health-related consumer products used by consumers of all ages. Older consumers are disproportionate users of some FDA-related products, in particular prescription drugs. FDA, therefore, should take the particular needs and limitations into account in this and all other regulatory proceedings. Many older persons are chronically ill, and research shows that they may be more susceptible to fraudulent behavior.¹ In addition, many older persons experience diminished vision and cognitive abilities, and FDA must take this fact into account as it considers various alternative approaches to product labeling and advertising.

Before addressing some of the specific issues and questions raised in the Notice, we would like to make some general observations. The focus of this notice is on FDA's authority over product-related information. With consumers now taking a more active role in their health care than ever before, they need more information. However, what is necessary is not just *any* information; rather, it is information that facilitates consumer choice, and information that is objective, accurate and not misleading.²

¹ See, e.g., AARP, CONSUMER BEHAVIOR, EXPERIENCES, AND ATTITUDES: A COMPARISON BY AGE GROUPS 8 (1999) ("Older consumers' susceptibility to unfair and deceptive business practices is compounded by their tendency to have lower annual incomes and lower levels of educational attainment, the two other major factors that predict a high level of consumer vulnerability.")

² We believe that it is important for FDA to distinguish between the different types of information that can appear on labels and in ads. "Objective" information -- for example, a list of product ingredients and of possible side effects -- is the type of data that consumers need in

AARP strongly supports the greater role that consumers are playing in their health care decisions and, for this reason, we endorse regulatory initiatives (like mandatory nutrition labeling for food and mandatory "medguides" for prescription medicines) that would empower consumers by providing them with information that is essential to effective decision-making. We also believe that direct-to-consumer advertising of prescription drugs, when it provides balanced, accurate information, can be useful to consumers.

The consequences of relying on misleading, inaccurate, health-related information cannot be underestimated: they can be serious -- even life threatening. A consumer may reject a proven treatment for a disease and, instead, choose a particular product based on an inadequately substantiated claim about its ability to prevent or treat the particular condition. If the product chosen by the consumer does not, perform as claimed, the consumer, at the very least, will be harmed economically; at the very worst, his health and safety may be seriously jeopardized.³

Reliance on misleading information on product labels and in advertisements can have a more insidious effect. Not only might consumers lose confidence in the particular product, but they may also become skeptical about all health-related information that is included on product labels and in advertisements.

The same result can occur when labeling and advertising claims are based on "preliminary evidence." All too often "preliminary evidence" is ultimately proven wrong.⁴ A

order to properly select and use products. This is the type of information that should be accorded broad protection under the First Amendment. We would like to see more of this type of information disclosed to consumers on product labels and in ads. Toward this end, we support including information about possible side effects on the labels of dietary supplement products and the listing of trans fat content on food labels.

By contrast, health claims (essentially claims about a particular ingredient's/nutrient's effectiveness in reducing the risk of a particular disease) do not provide the same kind of objective information. There exists significant disagreement about the appropriate quality and quantity of scientific evidence necessary to establish a health claim. Nevertheless, manufacturers are clamoring to include health claims on labels and in ads (and are challenging the FDA in court to let them do so) because they believe that the claims will help sell products.

If such claims are "inherently misleading," then they are not protected by the First Amendment. The controversy in this area centers around what is the most effective (and constitutionally permissible) approach to regulating claims that are "potentially misleading." We question whether misleading claims should be subject to the same level of protection under the First Amendment as the objective data discussed above.

³ Because of the impact that a purchase of a product based on a "health-related" claim can have on a consumer's health and safety, we believe that whenever a claim relates to a disease or health-related condition, it should be subject to the same standard -- whether it is made regarding a drug, dietary supplement, food, or any other FDA-regulated product.

⁴ See Food and Nutrition Board, Institute of Medicine, EVOLUTION OF EVIDENCE FOR

recently published report by the Institute of Medicine of the National Academy of Sciences uses the experience with beta-carotene to illustrate this problem. While an “impressive” body of evidence suggested that increased intake of foods rich in beta-carotene might reduce the risk of developing lung cancer, subsequent research suggests that increased consumption of beta-carotene actually *increased* the risk of cancer in high-risk populations.

AARP continues to strongly support FDA in its role of ensuring that the products it regulates are safe, effective (where appropriate), *and* accurately labeled. Courts have traditionally deferred to FDA on science-based decisions,⁵ and we believe FDA maintains the right to craft regulations based on its expertise. The recent First Amendment decisions that prompted this Notice do not undermine the Agency’s role to protect the health and safety of the public.

We urge FDA to continue to assert that courts should continue to defer to it, not simply on determinations of safety and efficacy, but also on decisions regarding the information that should be included on labels and in ads. This is because *all* of these judgments require the agency to review and evaluate scientific evidence. Just as consumers are ill equipped to assess the clinical studies that support a judgment that a drug is safe and effective, so too are they unqualified to determine whether a particular claim has adequate scientific support.⁶

SELECTED NUTRIENT AND DISEASE RELATIONSHIPS 6 (2002) (“An important finding is that preliminary evidence in support of a nutrient-disease relationship was often not confirmed.”)

⁵ See, e.g., Troy Corp. v. Browner, Nos. 96-5203, 96-5204, & 96-5188, 1997 WL 428500, at *5 (D.C. Cir. Aug. 1, 1997) (where an agency’s decision “rests on an evaluation of complex scientific data within the agency’s technical expertise,” it is entitled to “considerable deference”); Schering Corp. v. FDA, 51 F.3d 390, 399 (3d Cir.), *cert. denied*, 116 S. Ct. 274 (1995); A.L. Pharma, Inc. v. Shalala, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (the court noted the “high level of deference” due “an agency’s evaluations of scientific data within its area of expertise”); Berlex Lab., Inc. v. FDA, 942 F. Supp. 19, 25 (D.D.C. 1996) (“FDA’s policies and its interpretation of its own regulations will be paid special deference because of the breadth of Congress’ delegation of authority to FDA and because of FDA’s scientific expertise”).

⁶ See Bruce A. Silverglade, *The Vitamin Wars – Marketing, Lobbying, and the Consumer*, 13 J. PUB. POL’Y & MARKETING 152, 154 (1994) (“Consumers have no way of identifying whether a claim is based on a medical or health association study, a university-sponsored study, a manufacturer’s study, or no empirical evidence at all. Consumers have no method for distinguishing between truthful, beneficial claims based on emerging scientific research and those based on inconclusive, poorly designed studies or little scientific evidence.”).

II Discussion

A. The decision in *Thompson v. Western States Medical Center* does not preclude FDA from exerting its broad authority over product labeling and advertising.

1. FDA need not give the decision too expansive a reading.

This Notice was prompted by a number of recent court cases, most significantly, the Supreme Court decision in *Thompson v. Western States Medical Center*⁷. The case involved a First Amendment challenge to a provision of the Food and Drug Administration Modernization Act of 1996 (FDAMA). The provision prohibited pharmacists from advertising and promoting the availability of compounded drugs -- drugs that are custom-tailored by pharmacists or doctors to meet the needs of particular patients.

In the *Western States* case, the Supreme Court held that the government (both Congress and the FDA) failed to demonstrate, as is required by the First Amendment, that its restrictions on the advertising and promotion of compounded drugs are “not more extensive than necessary to serve its interest.” The Court determined that the government could have found several, alternative means of drawing a distinction between compounding and large-scale manufacturing of drugs that would have served the government’s legitimate interest and would not violate the First Amendment.

FDA need not give the *Western States* decision too broad a reading because its effect is limited to the specific, statutory provision governing the advertising and promotion of a certain type of drug. This decision does not necessarily apply to any other FDA regulations that have not been implemented pursuant to the FDAMA provision at issue in the *Western States* case. Moreover, it does not necessarily apply to other FDA-regulated products -- foods, dietary supplements, medical devices, or biologics. Most significantly, *Western States* does not hold that the First Amendment prohibits FDA from ever banning information from product labels and ads.

The *Western States* case only requires FDA to work with Congress to select an approach to distinguish compounded drugs from mass-marketed medicines that does not violate the First Amendment. FDA could decide to ban advertising and promotion of these drugs, but this time around, it must adequately support this choice and convince a court that there are no alternative approaches that are less restrictive of speech. If FDA selects an alternative approach to prohibiting speech, then that selection must also be sufficiently supported to withstand Constitutional challenge.

⁷ 122 S. Ct. 1497 (2002).

2. *FDA should wait to address the holding in Western States until it proposes a specific regulation that restricts labeling or advertising.*

The issue of how broadly the FDA should apply the *Western States* case, or any of the other recent court decisions, raises another threshold question: is it even appropriate for FDA to consider the issue of how recent First Amendment cases affect its regulations through a general, wide-ranging notice rather than a specific rulemaking proceeding.

We believe that the FDA should implement the holding in *Western States* when it next proposes a regulation that deals with product labeling or advertising. The decision would then require it to consider a range of approaches to regulating information and, when it ultimately selects a particular approach, to ensure that it is adequately supported. Congress and the FDA failed to do so in the *Western States* case and, for that reason, the advertising and promotional ban at issue there was declared unconstitutional.

3. *If FDA chooses to apply broadly the Western States decision, then it should not rush to embrace a particular approach to regulating labeling and advertising.*

The Court in *Western States* provides some guidance on possible alternatives to regulating speech that falls short of the outright ban that was held unconstitutional. It suggests that, in the area of compounded drugs, FDA could require a warning on all labels stating that “the drug had not undergone FDA testing and its risks are unknown.”⁸

FDA’s interest in this approach to regulating speech is clearly evident from the numerous questions included in this Notice about “warnings,” “disclaimers,” and “disclosures.”⁹ The

⁸ 122 S. Ct. at 1508.

⁹ Our comments will focus on “disclaimers” and “disclosures,” which are described in various ways but, for purposes of these comments, generally refer to “qualifying statements” that either provide additional information to clarify the extent of scientific support for a claim, indicate that the government agency has not reviewed or approved the claim, or state that the basis of the claim is not known.

Our comments will not address the questions in the Notice that relate to the use of warnings. We refer FDA to the extensive body of research that exists regarding the content and format of warnings, as well as the preambles to numerous federal regulations that have established warnings, including the FDA-required warnings relating to unpasteurized juices and shell eggs, the U.S. Department of Agriculture’s safe handling and cooking instructions for raw meat and poultry, and the alcohol warning label required by the Bureau of Alcohol, Tobacco, and Firearms. See, e.g., James R. Bettman et al., *Cognitive Considerations in Designing Effective Labels for Presenting Risk Information*, 5 J. PUB. POL’Y & MARKETING 1 (1986); Elzbieta Lepkowska-White and Amy L. Parsons, *Comprehension of Warnings and Resulting Attitudes*, 35

decision in at least one other case, *Pearson v. Shalala*,¹⁰ appears to endorse the use of disclosures and disclaimers. The D.C. Circuit in the *Pearson* case held that the First Amendment prevents FDA from prohibiting the use of a health claim for a dietary supplement product that does not meet the “significant scientific agreement” standard so long as the use of a “qualifying statement” (a disclosure) in conjunction with the claim prevents consumer deception.

The *Pearson* court did recognize, however, that there are limits to the use of disclaimers and disclosures. It created three major exceptions to its holding, situations in which FDA could prohibit a health claim and not consider allowing a claim with a qualifying statement:

- when permitting a health claim with a qualifying statement would threaten consumer health and safety;
- when scientific evidence supporting a health claim is outweighed by evidence that is qualitatively or quantitatively superior; or
- when empirical evidence demonstrates that a qualifying statement is insufficient to protect consumers from deception.

The remainder of our comments will highlight some of the problems associated with the use of disclaimers and disclosures and suggest some of the issues that the FDA must address before it adopts this particular approach to regulating information on product labels and in ads.¹¹

J. CONSUMER AFF. 279 (2001); K.R. Laughery et al., *The Noticeability of Warnings on Alcoholic Beverage Containers*, 12 J. PUB. POL’Y & MARKETING 38 (1993). Professor Laughery of Rice University is one of the leading experts in the area of human factors research. His research has shown that warnings printed on the front label, horizontally, and printed with a red pictorial warning are noticed most quickly.

¹⁰ 164 F.3d 650 (D.C. Cir. 1999).

¹¹ Given the complexity of the issues raised by this Notice, and the amount of research that exists relating to disclaimers and disclosures in both the legal and social science literature, we recommend that FDA establish an advisory committee, comprised of experts in the relevant fields, to review all of the research and make some specific recommendations. Alternatively, it may be appropriate to ask the National Academy of Sciences to undertake such a study.

B. Requiring widespread use of disclosures or disclaimers in labeling or advertising will not necessarily eliminate misleading impressions or remedy consumer confusion.

While adding more information to a label or advertisement through disclosures or disclaimers may be appropriate in some situations, practical experience with disclaimers and disclosures in various other legal areas, coupled with the results of a substantial body of social science and marketing research, call into question whether disclaimers and disclosures do what they are intended to do: eliminate misleading impressions and remedy consumer confusion.

1. FDA should carefully examine the research related to the theory of “information overload” before it requires more widespread use of disclosures and disclaimers on labels and in advertisements.

Many marketing and social science researchers have identified and examined a theory known as “information overload.” This theory suggests that, when faced with an overabundance of data, consumers will completely ignore most or all of the information presented to them.¹²

¹² James R. Penzer, *Note: Grading the Report Card: Lessons from Cognitive Psychology, Marketing, and the Law of Information Disclosure for Quality Assessments in Health Care Reform*, 12 YALE J. REG. 207, 238-239 (1995) (citing Jacob Jacoby et al., *Brand Choice Behavior as a Function of Information Load*, J. MARKETING RES. 63, 63-69 (Feb. 1974); Jacob Jacoby et al., *Brand Choice Behavior as a Function of Information Load: Replication and Extension*, 1 J. CONSUMER RES. 33, 33-42 (1974) (confirming earlier findings of decline in purchasing performance with increasing product information load and concluding that there are finite limits to consumers’ ability to accommodate substantial amounts of data within limited time span); Jacob Jacoby, *Perspectives on Information Overload*, 10 J. CONSUMER RES. 432, 435 (1984)).

In support of the information overload theory, Penzer also cited to two additional studies: Debra L. Scammon, *“Information Load” and Consumers*, 4 J. CONSUMER RES. 148, 148-55 (1977) (finding that increased information load causes consumers to divide their attention and results in poorer recall and increased information load may impart more knowledge but has little demonstrable effect on attitudes, behavior, or brand preference); James R. Bettman et al., *supra*, note 7, at 7 (pointing out that main issue in presenting information on warning labels is to provide sufficient information for informed choices but not so much that consumers process it selectively and suboptimally).

Overload analysis has been applied to a wide range of disclosure schemes,¹³ and researchers have found that decision effectiveness, defined as the ability to make optimal choices among alternatives in a set, varies directly with information quality and inversely with information quantity.¹⁴ Moreover, optimal levels of information disclosure will vary with the type of consumer population and the type of information presented, either graphic, verbal, or numerical.¹⁵

Overload theory remains somewhat controversial, and there appears to be an on-going debate regarding the appropriate research methodology¹⁶ and whether the phenomenon actually *does*¹⁷ – or *can* occur.¹⁸ Nevertheless, the theory continues to be invoked,¹⁹ and should be

¹³ See Penzer, *supra* note 10, at 239. Penzer noted that information overload has been applied to warning labels (Wesley A. Magat & W. Kip Viscusi, INFORMATIONAL APPROACHES TO REGULATION 90-105 (1992)); new home warranties (Jeff Sovern, *Toward a Theory of Warranties in Sales of New Homes: Housing the Implied Warranty Advocates, Law and Economics Mavens, and Consumer Psychologists Under One Roof*, 1993 WISC. L. REV. 13 (1993)); mortgage rules (William N. Eskridge, Jr., *One Hundred Years of Ineptitude: The Need For Mortgage Rules Consonant with the Economic and Psychological Dynamics of the Home Sale and Loan Transaction*, 70 VA. L. REV. 1083 (1984)); and prescription drug information (Comment, *Pharmaceutical Manufacturers and Consumer-Directed Information -- Enhancing the Safety of Prescription Drug Use*, 34 CATH. U. L. REV. 117, 145-47 (1984)).

¹⁴ *Id.* (citing Kevin L. Keller & Richard Staelin, *Effects of Quality and Quantity of Information on Decision Effectiveness*, 14 J. CONSUMER RES. 200, 200-213 (1987)).

¹⁵ *Id.* (citing Jacoby et al., *Replication and Extension, supra* note 10, at 41; Naresh K. Malhotra et al., *The Information Overload Controversy: An Alternative Viewpoint*, J. MARKETING 27, 35 (Spring 1982)).

In its own research, discussed *infra*, the Federal Trade Commission (FTC) found that, when testing different types of disclosures for foods that both make a health claim and contain a “negative” nutrient, “direct, verbal disclosures” (e.g. “high in saturated fat”) appear to be more effective than quantitative disclosures (e.g. “contains 2 grams of saturated fat”) to convey that a good food may not be healthful in all respects. Bureaus of Economics and Consumer Protection, Federal Trade Commission, *Generic Copy Test of Food Health Claims in Advertising* 28 (1998). Independent research corroborates this conclusion. See J. Craig Andrews, R. Netemeyer, & Scot Burton, *Consumer Generalization of Nutrient Content Claims in Advertising*, 62 J. MARKETING 62 (1998) (“Evaluative disclosures reduce misleading generalizations to a greater extent than do absolute or relative disclosures.”).

¹⁶ See Naresh K. Malhotra, *Information Load and Consumer Decision Making*, 8 J. CONSUMER RES. 419, 427 (1982).

¹⁷ One of the most prominent researchers in this area, Jacob Jacoby has suggested that consumers may actually unconsciously avoid overload by selectively accessing subsets of

thoroughly examined by FDA. FDA should carefully review the relevant studies that we have cited in our comments, and, perhaps, conduct a public hearing where it can question the leading experts in this area, as it considers more widespread use of disclaimers and disclosures on product labeling and in advertising.

2. FDA should review the existing research on the disclosures and disclaimers that are currently required for some of the products it regulates.

Disclosures and disclaimers are currently required for a number of FDA-related products. For example, the Dietary Supplement Health and Education Act of 1994 (DSHEA) requires that the label of any dietary supplement product that contains a "structure/function" claim include the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

One research study involving the DSHEA-mandated disclaimer found that consumers do not interpret this disclaimer as many assumed they would. The study found that consumers evaluated the claim in diverse ways: several participants in the study evidently were unaware of the lack of substantiation of the claims because they had either never read the disclaimer or had simply misread it to say that FDA had in fact evaluated the claim.²⁰

A survey commissioned by the AARP Public Policy Institute on dietary supplement use and knowledge among older consumers confirms that the DSHEA disclaimer may not function

presented information and, as a result, choices will be based on only a fraction of the significant data. Penzer, *supra* note 10 at 238-239 (citing Jacob Jacoby, *Perspectives on Information Overload*, 10 J. CONSUMER RES. 432, 435 (1984)).

¹⁸ See Naresh K. Malhotra, *supra* note 14; Naresh K. Malhotra, *Reflections on the Information Overload Paradigm in Consumer Decision Making*, 10 J. CONSUMER RES. 436, 439 (1984).

¹⁹ See, e.g., M. Teisl and B. Roe, *The Economics of Labeling: An Overview of Issues for Health and Environmental Disclosure*, AGRICULTURAL & RESOURCE ECONOMICS REV. 140, 148 (October 1998) (" . . . simply increasing the amount of information on a label may actually make any given amount of information harder to extract . . . This may cause individuals without the time or ability to process information to ignore it . . . leading to less optimal purchasing decisions") (citations omitted).

²⁰ Marlys J. Mason and Debra L. Scammon, "Product and Brand Decisions in a Complex Information Environment: The Case of Supplements," working paper, Department of Marketing, University of Utah, *discussed in* Marlys J. Mason and Debra L. Scammon, *Health Claims and Disclaimers: Extended Boundaries and Research Opportunities in Consumer Interpretation*, 19 J. PUB. POL'Y & MARKETING 6 (Spring 2000).

as intended. More respondents in our study indicated that they had either never seen the disclaimer or didn't know if they had ever seen it (59 percent) than had said that they did (41 percent).²¹

Numerous other disclosures and disclaimers, in addition to the DSHEA disclaimer, are mandated for various FDA products, and the agency should thoroughly review all of the existing research on their effectiveness as part of this proceeding.²²

3. *FDA should also consider the Federal Trade Commission's experience with "affirmative disclosures" along with the results of related research, some of which suggests that these disclosures are often ineffective.*

The Federal Trade Commission (FTC), which regulates the advertising of most products, (including FDA-regulated products like foods, dietary supplements, and over-the-counter (OTC) drugs) has required certain companies to include additional information (what it calls "affirmative disclosures") in advertisements when it has determined that the disclosure of this information is necessary to eliminate consumer deception.²³ This remedy is also employed when the contents of an ad are vague or ambiguous in a material way, thereby requiring clarification.²⁴

Some researchers have questioned the effectiveness of affirmative disclosures. One study tested possible disclosures (called "remedial statements") that were proposed by FTC staff for use in ads for two OTC drugs. FTC staff believed that the proposed disclosures would inform consumers that, in the opinion of some authorities, the evidence in support of the claims was insufficient. The study concluded, however, that the disclosure statements developed by the FTC would be widely misunderstood by large segments of the population.²⁵

The FTC staff has also conducted consumer research on "affirmative disclosures" in food advertising. In its "Enforcement Policy Statement on Food Advertising," released in 1994,²⁶ the

²¹ See Attachment 1 for a copy of these survey results.

²² The Nutrition Labeling and Education Act of 1990 mandates a number of disclosures for food products. For example, the food labeling rules that govern "nutrient content claims" require disclosures when more than a set amount of an "unhealthy" nutrient is present in a product that bears a claim regarding a "healthy" level of a different nutrient.

²³ See, e.g., *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489 (1st Cir. 1989).

²⁴ George Eric Rosen and Peter Eric Rosen, 2 THE LAW OF ADVERTISING §18.04[1] (1999) (footnotes and citations omitted).

²⁵ See Jacob Jacoby et al., *Corrective Advertising and Affirmative Disclosure Statements: Their Potential for Confusing and Misleading the Consumer*, 46 J. MARKETING 61 (1982).

²⁶ 59 Fed. Reg. 28388 (1994).

FTC stated that it will allow two general categories of health claims in food advertisements: (1) claims that had been approved for product labels by FDA (i.e. claims that the agency had determined were supported by “significant scientific agreement”); and (2) claims that were not approved by FDA if they are “expressly qualified to convey clearly and fully the extent of scientific support.”²⁷

In 1998, the FTC Bureau of Economics and Consumer Protection conducted research on possible disclosures that could accompany the second category of health claims. It tested different types of disclosure language to determine which was best able to help consumers understand the range of levels of evidence in support of claims. It found that “strong disclaimers” – explicit references to inconsistent study results or ongoing scientific debate such as “it’s too early to tell for sure” or “longer term research is needed” – had the greatest impact on consumer perceptions of the level of proof underlying a health claim.²⁸

Following up on this research, AARP included a related question in a recent telephone survey. Respondents were read two different claims:

“Increased consumption of foods like grape juice that are rich in antioxidants may reduce the risk of some cancers;” and

“Preliminary evidence suggests that increased consumption of foods like grape juice that are rich in antioxidants may reduce the risk of some cancers but further research is necessary.”

They were then asked to compare the two claims in terms of the level of scientific support. Fifty-two percent of respondents thought that the second claim – which included the type of “qualifying language” that the FTC suggests is acceptable -- was supported by more scientific evidence than the first, with 16 percent believing the opposite, and 22 percent thinking that the claims had the same level of scientific support. This perplexing result demonstrates the need for further research in this area.

4. *FDA should examine the use of disclosures in other areas of the law, in particular trademark law.*

Disclaimers are often used in trademark law to reduce the likelihood of consumer confusion. If corporation X has a product, with a trademarked name, and corporation Y introduces a competing product with a similar name, then Y might be required to include a disclosure in its advertising, which indicates that its product is “not manufactured or authorized by corporation X.” The effectiveness of this approach has been called into question by a recent

²⁷ 59 Fed. Reg. at 28394.

²⁸ *GTC Report*, *supra* note 13, at E8.

review of trademark disclaimer cases, which concluded that in those cases in which disclaimers were examined empirically, they generally were found to be ineffective at alleviating consumer confusion.²⁹

We refer FDA to other areas of law where disclosures and disclaimers are employed,³⁰ and recommend that it carefully examine these as it considers more widespread use of a disclosure/disclaimer approach.

5. *There are a number of issues that require further research before FDA mandates wider use of disclosures and disclaimers.*

The studies discussed above highlight the need for further research in a number of areas, including:

Disclaimer/disclosure context: In the past, disclaimers (other than warnings) have been used most commonly in advertising and supplemental materials rather than on labels.³¹ Further research is necessary to determine whether disclaimers and disclosures are effective on labels.³²

Disclaimer/disclosure content: Disclaimers and disclosures have generally been used to make affirmative, objective statements about products and not to alert consumers that claims have not been tested and the basis for them is not known. Experience with the DSHEA disclaimer calls into question the value of the latter type of disclosure, so more research in this area is also advisable.

Disclaimer/disclosure format: Disclaimers are useless if consumers cannot actually read them. While the FTC generally requires that affirmative disclosures be "clear and conspicuous," empirical research demonstrates that this standard does not necessarily ensure readability.³³ Specific format requirements address the needs of particularly

²⁹ Jacob Jacoby and Maureen Morrin, "Not Manufactured or Authorized by . . .": Recent Federal Cases Involving Trademark Disclaimers, 17 J. PUB. POL'Y & MARKETING 97, 14 (1998)

³⁰ See *supra* note 11.

³¹ Mason and Scammon, *supra* note 18, at 5.

³² Also relevant are consumer attitudes regarding labels and advertisements. Our telephone survey confirmed the general assumption that consumers are more likely to believe information that appears on labels (67 percent of our respondents) more than information in advertisements. See Attachment 2 for a copy of these survey results.

³³ See, e.g. Mariea Grubbs Hoy and Michael J. Stankey, *Structural Characteristics of Televised Advertising Disclosures: A Comparison with the FTC Clear and Conspicuous*

vulnerable consumers – like older consumers who may have impaired vision and cognitive abilities³⁴ – and should be tested to determine which ones best ensure readability.³⁵

6. ***Before it is required in a particular situation, a specific disclosure or disclaimer should be tested on consumers to ensure that it actually is effective.***

The research discussed in these comments clearly demonstrates the need to test disclaimers and disclosures on actual consumers before determining, which, if any, should be included on product labels or in advertising. As the FTC cautioned when it released its *GCT Report*, “it is important to recognize . . . that subtle changes in the wording or placement of claims and qualifying disclosures could have a significant impact on how consumers interpret an advertisement.”³⁶

In trademark cases, courts were initially reluctant to rely on consumer survey evidence in arriving at their decisions but, in recent years appear to have increased their reliance on such evidence.³⁷ The court in *Pearson* acknowledges that empirical evidence has a role to play in

Standard, 22 J. ADVERTISING 47 (1993); Darrel D. Muehling and Richard H. Kolbe, *A Comparison of Children’s and Prime-time Fine-Print Advertising Disclosure Practices*, 27 J. ADVERTISING 37 (1998). See also Jacoby and Morrin, *supra* note 27, which found that, even when efforts were made to make a disclaimer more prominent or to increase the number of exposures, a significant proportion of consumers still failed to report the correct source of the products (which is the goal of a trademark disclaimer).

³⁴ See Medguide Report, Appendix G, for a list of formatting elements that are generally regarding as enhancing readability.

³⁵ Another issue that should be studied is the impact that consumers’ assumptions regarding the operation of governmental bodies could have on the usefulness of disclaimers. See Jacoby and Morrin, *supra* note 27, at 15-16 (“If consumers do not process disclaimer information because they operated under an implicit theory that the government “must have” checked on the safety of such a product before allowing a manufacturer to distribute it, it could have undesirable effects on the public welfare.”).

Our recent telephone survey draws attention to this point: 79 percent of respondents believed that the government must review and approve all health-related claims before they can appear on dietary supplement labels, when this is not the case.

³⁶ Press Release, “FTC Releases the Food Copy Test Results” (Nov. 18, 1998).

³⁷ Jacoby and Morrin, *supra* note 27, at 6 (citing Jacob Jacoby, “Survey and Field Experimental Evidence,” in *THE PSYCHOLOGY OF EVIDENCE AND TRIAL PROCEDURE*, 175 -200 (1995)).

determining the effectiveness of disclaimers and disclosures.³⁸

We urge FDA to require that any disclaimer or disclosure that is being proposed for a label or advertisement be tested on real consumers in real-life situations. FDA should review the testing methods used in various areas (e.g., FTC and trademark cases) and identify acceptable testing methodologies. We also believe that any proposed disclaimer or disclosure should be tested on a wide range of consumers of different ages and different educational levels.³⁹

One question is who should be responsible for the testing. Given the FDA's limited budget, and the often greater resources available in the private sector, we believe that, as appropriate and subject to FDA oversight and approval, the manufacturer could conduct the testing.

III Conclusion

While we believe the FDA should take into account recent court cases, in particular, the *Western States* decision, on its authority to regulate labeling and advertising regulations, we caution the agency not to overreact and too quickly adopt a particular approach to labeling and advertising. We believe that *Western States* has limited impact on FDA's authority in this area and that it applies only to the specific statutory provision in question.

Moreover, in weighing the impact of the relevant court cases and considering alternative approaches in this area, FDA must balance them against the approach to labeling and advertising that it has followed for decades, an approach that we believe has benefited consumers by providing them with essential information while protecting them from false and misleading claims that could result in significant harm.

For this reason, we believe that the agency has a significant burden to meet before adopting a different approach to product labeling and advertising. The agency must thoroughly and thoughtfully examine the relevant legal and social science literature discussed in these comments before moving forward. In addition, there is a clear need for additional research, which we believe the FDA should conduct before coming to any decisions in this proceeding.

³⁸ *Pearson*, 164 F.3d at 659-60 (stating that the court "does not rule out" the possibility that the government could demonstrate with empirical evidence that disclaimers would bewilder consumers and fail to correct for deceptiveness).

³⁹ See Christine Moorman and Linda L. Price, *Consumer Policy Remedies and Consumer Segment Interactions*, 8 J. PUB. POL'Y & MARKETING 181 (1989) (we need to look not just at the costs and benefits but also at the distributional effects of an information remedy on specific consumer segments).