



GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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March 28, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Guidance on Significant Scientific Agreement
Docket No. 99D-5424
64 Fed. Reg. 71794 (December 22, 1999)

The Grocery Manufacturers of America (GMA) is the world's largest association of food, beverage, and consumer brand companies. With consumer sales of more than \$460 billion, GMA member companies employ more than 2.5 million workers in all 50 states. GMA speaks for food and consumer brand manufacturers at the state, federal, and international levels on legislative and regulatory issues.

GMA has previously submitted comments to FDA on May 11, 1999 on the proper interpretation and implementation of the disease prevention/treatment claims provisions for food in Sections 403(r)(1)(B) and 403(r)(3)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which were added by the Nutrition Labeling and Education Act of 1990, and filed a brief amicus curiae in Nutritional Health Alliance v. Shalala, 144 F.3d 220 (2d Cir. 1998) on November 13, 1997 on the same subject. Copies of the prior GMA comments and brief are attached to these comments. GMA submits these additional comments specifically to address the continuing lack of proper implementation by FDA of the provisions of the FD&C Act governing disease prevention/treatment claims for food.

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The guidance properly reflects the fact that the decision in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), rehearing en banc denied, 172 F.2d 72 (D.C. Cir. 1999), and the “significant scientific agreement” standard, apply to all food -- conventional food, dietary supplements, and all other categories of food regulated under the FD&C Act with the single exception of medical food. This is in contrast with the prior notice of the agency’s strategy to implement the Pearson decision published in 64 Fed. Reg. 67289 (December 1, 1999), which inexplicably and unlawfully restricts implementation of the Pearson decision to disease prevention/treatment claims for dietary supplements.

The guidance continues, however, to reflect an unlawful and unconstitutional interpretation of the disease prevention/treatment claims provisions of the FD&C Act. Section 403(r)(3)(B)(i) requires only that a disease claim itself be supported by significant scientific agreement. It does not require that the relationship between a food substance and a disease condition be established by significant scientific agreement, except to the extent that the claim characterizes that relationship. There is a clear difference between (1) a claim that describes that relationship as established, and (2) a claim that describes that relationship in terms of preliminary data or emerging science, or consists of a factual statement about the current status of scientific research, or reports on the findings and recommendations of authoritative nongovernment scientific bodies. In either case, the only issue to be addressed by FDA, under Section 403(r)(3)(B)(i), is whether the claim is established by significant scientific agreement. In the latter case -- where the claim relates to preliminary data or emerging science, the status of scientific research, or the findings and recommendations of authoritative nongovernment scientific bodies -- FDA has no statutory discretion to deny the claim if the existing evidence,



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8547 '00 MAR 29 18:21

May 11, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
Parklawn Building
5630 Fishers Lane
Rockville, Maryland 20852

Re: Disease Prevention Claims and Nutrient Descriptors
Based Upon Authoritative Statements of Federal
Health Agencies and the National Academy of Sciences
Docket No. 99N-0554
64 Fed. Reg. 14178 (March 24, 1999)

The Grocery Manufacturers of America (GMA) is the world's largest association of food, beverage, and consumer brand companies. With consumer sales of more than \$450 billion, GMA member companies employ more than 2.5 million workers in all fifty states. GMA speaks for food and consumer brand manufacturers at the state, federal, and international levels on legislative and regulatory issues. GMA and its member companies have a deep interest in the use of truthful and nonmisleading disease prevention claims and nutrient descriptors based upon authoritative statements by federal health agencies and the National Academy of Sciences.

The GMA position on the FDA implementation of the disease prevention claims provision in the Nutrition Labeling and Education Act of 1990 generally, and on the authoritative statement amendment in the Food and Drug Administration Modernization Act of 1997 specifically, have previously been well-documented. GMA submitted a brief amicus curiae in Nutritional Health Alliance v. Shalala, 144 F.3d 220 (2d Cir. 1998), criticizing FDA implementation of the disease prevention provisions and arguing that this implementation

violates the First Amendment to the United States Constitution. A copy of that brief (without appendices) is attached to these comments as Appendix A. GMA also submitted comments in February 1998 to FDA Deputy Commissioner Michael A. Friedman, M.D., outlining a recommended approach to the authoritative body provision. A copy of this letter is attached to these comments as Appendix B. These two documents form the basis for many of the points made in these comments.

Executive Summary

GMA recommends that the entire constricted FDA approach to disease prevention claims be reconsidered and revised, for two reasons. First, the present approach is not required by, and does not comply with, the statutory provisions set forth in the Nutrition Labeling and Education Act of 1990. Second, the current FDA approach to implementation of this provision violates the First Amendment, as interpreted in the recent decision in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999).

Congress enacted the authoritative statement provision in the Food and Drug Administration Modernization Act of 1997 as an explicit rejection of the FDA existing regulations governing disease prevention claims. Accordingly, the authoritative statement provision should be implemented in an expansive and flexible way.

In these comments, GMA provides a specific response to each of the questions FDA has posed in the notice on this matter. Congress placed no limit on the source of an authoritative statement other than it must represent the position of the agency and not the position of an individual. An authoritative statement by a federal health agency is any published

statement by that agency that is issued by the agency itself and not by an individual within the agency. It need not be designated specifically as "authoritative." The fact that a federal health agency publishes a statement within its expertise is sufficient, in itself, to determine that the statement is authoritative.

The significant scientific agreement standard applies to disease prevention claim based upon authoritative statements in the following way. Any truthful and nonmisleading statement about the scientific status of a diet/disease relationship must be regarded as acceptable, regardless whether a definitive causal relationship has been proved. As long as a federal health agency publishes a statement about the existing status of the science relating to a diet/disease relationship, and it is in fact a truthful and nonmisleading statement, the significant scientific agreement standard has been met. This is explicitly reflected in the legislative history of the FDA Modernization Act of 1997.

GMA urges FDA to reconsider and revise its existing regulations governing disease prevention claims in 21 C.F.R. 101.14, in order to bring them into compliance with the statutory provisions and the First Amendment. FDA must abandon the concept that no truthful and nonmisleading statement about emerging science in the area of diet and health may lawfully be made in food labeling. In its place, FDA must construct reasonable ways to communicate diet/disease information that is not yet definitive, with appropriate explanation and disclaimers, in order better to inform the public about this important area of personal health.

The federal health agencies encompassed within the authoritative statement provision include such a broad array of federal agencies that no purpose would be served by

attempting to provide a list. Dietary supplements should be handled in the same way as conventional food. There is no need to specify, in detail, the contents of a premarket notification submitted to FDA for a disease prevention claim based on an authoritative statement. There is also no statutory or other legal basis for requiring such a premarket notification to include an analytical method for measuring the substance that is the subject of the claim. A general survey of the applicable literature is sufficient to satisfy the requirement of a balanced representation of the scientific literature. The existence of a premarket notification should be regarded as confidential until the 120-day period ends, and thereafter any proprietary scientific research set forth in the premarket notification should continue to be regarded as confidential because it requires an investment and represents confidential business information. If FDA wishes to challenge a premarket notification, the only ways to do so are to issue a final regulation or to obtain a court order banning the proposed disease prevention claim.

The authoritative statement provision has less applicability to nutrient descriptors than to disease prevention claims, but GMA believes that it should in any event be applied in the same way to both areas.

I. The Entire Constricted FDA Approach To Disease Prevention Claims Must Be Reconsidered And Revised

GMA urges FDA to use this occasion to reconsider and revise its entire constricted approach to the use of truthful and nonmisleading disease prevention claims in food labeling.

A. FDA Implementation of the Disease Prevention Claims Provision in the 1990 Act Was Not Required by, and Does Not Comply With, the Statutory Provisions

Section 403(r)(3)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Nutrition Labeling and Education Act of 1990, prohibits any claim that "characterizes the relationship of any nutrient...to a disease or a health-related condition" unless FDA has approved that claim through promulgation of a regulation. Section 403(r)(3)(B)(i) authorizes FDA to promulgate a regulation approving a disease prevention claim if the "totality of publicly available scientific evidence" demonstrates that there is "significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."

In implementing this statutory provision, FDA has interpreted it expansively to broaden the scope of claims subject to the premarket approval requirement, and has sharply narrowed the circumstances in which any such claim may be approved. The net result has been a constricted approach that suppresses truthful and nonmisleading disease prevention information from reaching the consuming public.

FDA expanded the scope of this provision, beyond that intended by Congress, by broadly including any form of communication that associates a food with an improvement in health. Nothing in the statute required or even authorized this expansive result. The disease prevention claim provision could have been interpreted much more narrowly to apply only to statements in which manufacturers in fact "characterize" the relationship between a nutrient and a disease or health-related condition. Such an approach would have allowed the food industry to

make factual statements about the status of scientific research or the recommendations and findings of authoritative scientific bodies without subjecting these statements to FDA approval. Under this approach, factual statements of this nature would be regulated by FDA under the provisions of the FD&C Act that prohibit false or misleading labeling. By taking an unnecessarily broad approach, in contrast, FDA has prohibited the use of all statements describing important new scientific studies, even when qualified accurately to reflect the nature of the scientific evidence relied upon. No such result was intended by Congress.

At the same time, FDA dramatically narrowed the criteria for approval of disease prevention claims. FDA could have issued regulations categorically approving all truthful and nonmisleading statements describing the state of the scientific evidence, or the conclusions and recommendations of expert scientific bodies with respect to diet and disease relationships. Instead, FDA regulations have required that the validity of the diet/disease relationship to which a statement refers must itself be the subject of significant scientific agreement -- which FDA has interpreted to be a virtual consensus of scientists. Once again, there is nothing in the statute that required or even justifies this approach. It has further restricted and suppressed the dissemination of useful health information to the consuming public, contrary to the clear intent of Congress.

GMA urges FDA to abandon these two approaches. The scope of the disease prevention claims provision should be narrowed to specific claims about diet/disease relationships. Truthful and nonmisleading claims about the state of the scientific evidence

should be approved without the need to demonstrate that such a relationship has itself been proved.

B. The Current FDA Approach to Implementation of the Disease Prevention Claims Provision Violates the First Amendment

As documented in the attached GMA brief amicus curiae in the Nutritional Health Alliance case, the FDA implementation of the disease prevention claims provision cannot withstand scrutiny under the First Amendment to the United States Constitution. The GMA position set forth in this brief has subsequently been sustained in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). In that case, a unanimous panel of the District of Columbia Circuit -- reflecting both liberal and conservative viewpoints -- held that disease prevention claims could not be completely suppressed by FDA. The court required FDA to permit such claims with appropriate disclaimers or other information that would assure that they are truthful and not misleading.

The First Amendment does not permit FDA to function as a national censor on the provision of truthful and nonmisleading scientific information to the public. The Supreme Court has repeatedly struck down broad prophylactic bans on truthful and nonmisleading commercial speech of the type involved here:

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.

44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996). As another court recently stated in a First Amendment case, FDA "exaggerates its overall place in the universe" in attempting to

suppress scientific information that it has not approved. Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51, 67 (D.D.C. 1988).

The Supreme Court has observed that "bans against truthful, nonmisleading commercial speech rarely seek to protect consumers from either deception or overreaching, they usually rest solely on the offensive notion that consumers will respond 'irrationally' to the truth." 44 Liquormart, Inc., 517 U.S. at 503 (1996). As the Supreme Court recognized in Ruben v. Coors Brewing Co., 514 U.S. 476, 491 (1995) in striking down a BATF prohibition of truthful information about the alcohol content of beer, regulatory alternatives are available that "could advance the Government's asserted interest in a manner less intrusive to respondent's First Amendment rights."

FDA has itself recognized that the suppression of information on the scientific status of research on diet/disease relationships can directly harm the public health because

...if claims that are likely to be true are removed, this will decrease the total benefits of the 1990 Amendments as consumers will lose valuable information.

56 Fed. Reg. 60856, 60869 (November 27, 1991). This result can be avoided by taking the approach recommended by GMA above, permitting truthful and nonmisleading statements about the status of scientific research without the requirement of specific FDA premarket approval -- the approach Congress intended when it enacted this provision in the Nutrition Labeling and Education Act of 1990.

The First Amendment, as interpreted and applied in these and other judicial precedents, thus requires FDA to reconsider and substantially revise its entire approach to disease prevention claims. GMA urges FDA to adopt the approach recommended above.

C. Congress Enacted the Authoritative Statement Provision in the FDA Modernization Act as an Explicit Rejection of the Agency's Existing Regulations Governing Disease Prevention Claims

Congress never intended to provide FDA with the authority to censor truthful and nonmisleading information about the state of scientific research relating to diet and disease. Rather, it intended FDA to have premarket approval authority only over direct claims that a particular nutrient has in fact been shown by appropriate scientific testing to prevent a specific disease.

When FDA expanded its authority as described above, Congress reacted by enacting the authoritative statement provision contained in the FDA Modernization Act of 1997. This was an explicit determination by Congress that FDA had gone much too far with its implementation of the disease prevention claims provision in the Nutrition Labeling and Education Act, and that the public was entitled to obtain truthful and nonmisleading information about the current state of scientific evidence on diet/disease relationships before they mature to the point of a proven disease prevention claim that will be approved by FDA. Even if that were not the intent of Congress in the 1997 Act, the Pearson decision now requires this result.

D. The Authoritative Statement Provision in the FDA Modernization Act Should be Implemented in an Expansive and Flexible Way

FDA should not make the same mistake twice. It should not again take a constricted and narrow approach to a provision enacted by Congress as an explicit rejection of

the constricted and narrow approach taken by FDA to the disease prevention claims provision in the Nutrition Labeling and Education Act. It should not again implement this new provision in a way that violates the First Amendment as applied by the District of Columbia Circuit in the Pearson case. As GMA outlined in its letter to lead Deputy Commissioner Friedman in February 1998, and as reiterated below, FDA should recognize and implement the intent of Congress to authorize the use of any statement published by a federal health agency or the National Academy of Sciences that discusses the state of current scientific knowledge about diet and disease or that directly concludes that a causal relationship exists between a particular nutrient and a specific disease.

In the sections below, GMA responds directly to the questions FDA has posed in its Federal Register notice on this matter.

1. The Scientific Basis for Claims

a. Authoritative Statements

Congress placed no limit upon the source of an "authoritative statement" other than it must represent the position of the agency and not the position of an individual. The Senate Committee Report states, for example, that:

Important Federal public health organizations, as part of their official responsibilities, routinely review the scientific evidence pertinent to diet and disease relationships, and publish statements developed through such reviews.

That report cites the Surgeon General's Report on Nutrition and Health (1988) as well as pamphlets published by the National Cancer Institute and the National Heart, Lung, and Blood

Institute recommending dietary changes to reduce the risk of diseases about which those two Institutes have unique expertise.

These are merely illustrations of the types of publications that Congress intended to encompass within these new statutory provisions. Dissemination of this literature with food products, or extracting statements from these publications and reproducing or summarizing them in food labeling in an accurate and nonmisleading way, are fully thus within the intent of Congress on the scope of the authoritative statement provision.

There is no statutory requirement that an authoritative statement be labeled "authoritative" by the relevant agency or anyone else. The regulated industry is aware that FDA visited the agencies involved when it denied the first nine authoritative statements submitted to FDA. This is not within the congressional intent. Congress intended that an agency's public statements be regarded as authoritative if they were published under the name of the agency, not based on a subsequent designation given by an agency employee to FDA in response to an FDA inquiry. For that reason alone, FDA should discontinue any reliance on the views of agency employees about the "authoritative" status of agency statements.

b. The Definition of an Authoritative Statement

An authoritative statement by a federal health agency is any published statement by that agency that is issued by the agency itself and not by an individual within the agency. The only limitation placed upon the definition of an authoritative statement by Congress was the obvious point that it could not be made by an individual, e.g., in a speech or a letter. As noted above, any statements made by a federal health agency in writing automatically qualify under the

statute as an authoritative statement as long as they fall within the expertise of the agency involved.

c. Decisions About Authoritative Statements

The fact that a federal health agency publishes a statement within its expertise is sufficient, in itself, to determine that the statement is authoritative. Certainly, FDA should not be in a position to determine that a sister agency's statement is not authoritative. FDA discussion with an agency employee about the status of an agency statement will similarly be inappropriate, for the same reason that an employee's statement cannot be regarded as an authoritative agency statement.

FDA should ask itself why a federal health agency would publish a statement, using public funds, if it is not intended to be authoritative. Presumably, FDA does not publish statements that it intends to present less than authoritative views of the agency. There is no reason why other federal agencies are different.

The language of Section 403(r)(3) of the FD&C Act as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA), expresses the clear intent of Congress to extend available health claims for foods beyond those formally adopted by FDA. Congress intended that FDA's role in the use of health claims based on the statements of authoritative bodies to be largely ministerial. As such, Congress did not anticipate or encourage FDA to provide advise and consent to its sister agencies such as NIH and the Surgeon General's office in the deliberations of those bodies relating to diet and disease. Instead, FDA's role is to establish processes and procedures to facilitate the adoption of health related statements on food

labels which accurately reflect such authoritative statements without substantial health risk to American consumers. The terms of FDAMA do not provide veto power to FDA over the deliberation of authoritative bodies nor do they anticipate the agency's active participation in such deliberations.

There are, of course, federal agency documents that are clearly labeled as less than authoritative. Documents that are drafts, or that clearly show that they are working papers and not final statements, would not qualify. This would be true of any organization. Where an agency publishes a final statement, however, it must be considered as authoritative, as long as it is within the expertise of that agency.

There is no statutory basis for consulting with any official of an agency to ask whether a particular statement is authoritative. One official might regard a statement as particularly authoritative and another might regard it as less than authoritative, but once the agency itself publishes the document it is, *per se*, an authoritative statement. If it were not, it should never have been published in the first place and should promptly be disavowed and withdrawn.

d. The Context of Authoritative Statements

The context of a statement in a publication is relevant to determining whether that statement is authoritative only to the extent explained under the prior section. A statement labeled as a draft or a preliminary review does not qualify, because of the "context" of that clear denomination. An unqualified statement in an official publication of an agency, however, is *per se* an authoritative statement.

The context of a statement in an agency publication will, of course, be determinative of the type of claim that can be based upon that authoritative statement. A carefully worded and qualified authoritative statement must be accurately and truthfully conveyed in any claim based upon it. A broad and sweeping authoritative statement will justify a broad and sweeping claim. Thus, the context of an authoritative statement is of far greater importance in determining the type of claim that can be made than it is in determining whether the statement is authoritative.

Preliminary findings that reflect a general consensus of an authoritative body are an acceptable basis for a properly qualified health claim. For example, an initial finding by an authoritative body which indicates that people who consume diets high in a particular food or nutrient show lower instances of a certain disease or condition is sufficient justification for an appropriately qualified claim even though such a finding may be characterized as preliminary and in need of additional supporting information. FDA's role under such circumstances is not to assert that no statement can be made. Instead, the agency's statutory role is to assist the regulated industry in assuring such claims are appropriately qualified. This is also the role contemplated by recent judicial decisions applying well settled legal commercial speech protections under the First Amendment.

e. Significant Scientific Agreement on Authoritative Statements

The significant scientific agreement standard applies to disease prevention claims based upon authoritative statements in the following way. As explained in Part I of these comments, any truthful and nonmisleading statement about the scientific status of a diet/disease

relationship must be regarded as acceptable, regardless whether a definitive casual relationship has been proved. If three studies have been conducted with respect to a diet/disease relationship, two are negative and one is positive, and an expert federal health agency releases a statement summarizing the results of those three studies accurately and truthfully, it is GMA's position that there is significant scientific agreement on that statement and that statement should be permitted for use in food labeling. There is no need to show that there is significant scientific agreement that a casual relationship exists in the diet/disease relationship, and in fact under this hypothetical no such showing could possibly be made.

This point is made explicitly in the 1997 Senate report on the authoritative statement provision:

The new provision will allow a health claim in food labeling without FDA authorization, if it consists of or will otherwise summarize or reflect information contained in a publication of a Federal Government scientific organization or some component of the National Academy of Sciences.

Congress thus concluded that the significant scientific agreement component is met by publication of the authoritative statement itself.

The important point is that the federal agency review of the existing science relating to the matter has been accurately stated in a way that virtually all scientists would agree is accurate and truthful, and thus the public is entitled to receive this information as part of food labeling under the authoritative statement provision in the 1997 Act. The legislative history which explicitly refers to the common practice of Federal agencies to "review the scientific

evidence pertinent to diet and disease relationships" makes this position unmistakable. And even if it were not the clear intent of Congress, the First Amendment requires it.

2. Existing Regulatory Requirements

FDA must abandon the concept that no truthful and nonmisleading statement about emerging science in the area of diet and health may lawfully be made in food labeling. In its place, FDA must construct reasonable ways to communicate diet/disease information that is not yet definitive, with appropriate explanation and disclaimers, in order better to inform the public about this important area of personal health.

As explained in Part I of these comments, the existing FDA regulations governing disease prevention claims in 21 C.F.R. 101.14 must be reconsidered and revised in order to comply with the statutory provision relating to disease prevention claims generally, the statutory provision relating specifically to disease claims based on authoritative statements, and the requirements of the First Amendment as elucidated in the Pearson decision and other judicial precedent

3. Procedural and Definitional Issues

a. Federal Health Agencies

The federal health agencies encompassed within the authoritative statement provision include a broad array of federal agencies. No purpose would be served by attempting to establish a list of all applicable agencies if for no reason other than that the list will constantly change depending upon congressional enactment and appropriations. The statutory purpose will

not be served by limiting the applicable federal agencies to a finite list. Indeed, this would not comport with the First Amendment as interpreted in the Pearson decision.

b. Dietary Supplements

GMA strongly supports the use of authoritative statements as the basis for health claims in the labeling of dietary supplements, for two reasons. First, this complies with the principle of labeling parity between conventional food and dietary supplements as advanced by FDA in preambles to Federal Register notices during the past year. Second, there is no basis for distinguishing between conventional food and dietary supplements for purposes of disease prevention claims under the First Amendment.

c. Contents Of Notification

There is no need to specify, in detail, the contents of a premarket notification submitted to FDA for a disease prevention claim based on an authoritative statement. Clearly, the authoritative statement and the disease prevention claim must be set forth. Any other relevant material should also be included. This is best left up the person submitting the notification.

d. Analytical Methodology

There is no statutory or other legal basis for requiring a premarket notification for a disease prevention claim based on an authoritative statement to include an analytical method for measuring the substance that is the subject of the claim. In most instances, there will be analytical methodology that is recognized by FDA, the Association of Official Analytical Chemists, or other scientific organizations. There is no more reason to require submission of an

analytical method for purposes of a disease prevention claim based on an authoritative statement than there is for purposes of hundreds or thousands of other claims made for food and other consumer products throughout the country.

e. Balanced Scientific Literature

Section 403 (r)(2)(G)(ii)(III) of the FD&C Act requires that the premarket notification submitted to FDA 120 days before use of a disease prevention claim based upon an authoritative statement must include a balanced representation of the scientific literature relating to the nutrient level to which the claim refers. GMA believes that this requires a survey of the applicable literature and a brief summary, with references, that sets forth a balanced overview of that literature. There is no need to establish regulatory requirements to implement this provision.

f. Confidentiality of Notification

Premarket notifications made in accordance with the authoritative statement provision constitute confidential business information that is not subject to public disclosure until the 120-day period ends. The notification will contain highly competitive information that falls squarely within the exemption from public disclosure under the Freedom of Information Act. If FDA were to make premarket notifications public upon receipt, competitors could file copycat notifications and the competitive advantage for the initial submission would be destroyed. After completion of the 120-day notification period, the portion of the premarket notification that relates to any proprietary scientific research that represents confidential business information must be retained as confidential and may not be made public.

g. Inadequate Premarket Notifications

Under Section 403(r)(3)(D) of the FD&C Act, there are only two ways for FDA to prohibit a disease prevention claim based on an authoritative statement following submission of a premarket notification: a regulation or a court order. FDA may wish to send letters informing companies of the agency's enforcement intentions, but those letters have no legal effect.

II. Nutrient Descriptors

Although the statutory provisions relating to disease prevention claims and to nutrient descriptors based upon authoritative statements of federal health agencies are parallel, the different nature of these two types of claim must be taken into account. The nutrient descriptors provision in the Nutrition Labeling and Education Act requires FDA to define all significant nutrient descriptors for all recognized nutrients. In effect, the FDA regulations that have been promulgated under the nutrient descriptors provision constitute a dictionary of applicable descriptors. Like all dictionaries, the descriptor definitions are useful only insofar as they are applied consistently and uniformly throughout the country, in all media. Thus, it cannot be anticipated that a new definition of a term that has already been defined by FDA will be submitted in a premarket notification for a nutrient descriptor on the basis of an authoritative statement by another federal health agency.

There may, however, be two instances where this provision could be of importance. The first involves definitions of terms not yet defined by FDA, e.g., high or low in complex carbohydrates. The second involves alternative terminology for synonyms not yet included within a particular definition. In both of these instances, the general principles set forth above by GMA relating to disease prevention claims would also be applicable.

III. Conclusion

For the reasons set forth above, GMA urges FDA to reconsider and substantially revise all of its regulations governing disease prevention claims in order properly to reflect both the applicable provisions of the FD&C Act and the requirements of the First Amendment.



Lisa D. Katic, R.D.
Director, Scientific and Nutrition Policy



James H. Skiles
Vice President and General Counsel

Attachments

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

NUTRITIONAL HEALTH ALLIANCE, and SOO MAN SHIM,
d/b/a New Nutrisserie,

Plaintiffs-Appellants,

v.

DONNA SHALALA, in her official capacity
as Secretary, U.S. Department of Health and
Human Services, and DAVID KESSLER, Commissioner,
Food and Drug Administration,

Defendants-Appellees.

BRIEF OF THE GROCERY MANUFACTURERS OF AMERICA, INC.
AS AMICUS CURIAE
IN SUPPORT OF PLAINTIFFS-APPELLANTS

The Grocery Manufacturers of America, Inc. (GMA) submits this *amicus* brief in support of Plaintiffs-Appellants, who are seeking reversal of the district court's decision on First Amendment grounds. The parties have consented to the filing of this brief. Their written consents have been filed with the Clerk of the Court.

INTEREST OF THE AMICUS CURIAE

GMA is a 90-year-old national trade association comprising more than 130 companies that manufacture and market foods sold at retail grocery stores throughout the United States. GMA member companies produce a wide range of healthful and nutritious food products that make substantial

contributions to the public health. The health claim provisions adopted under the Nutrition Labeling and Education Act, Pub. L. No. 101-535, 104 Stat. 2353 (1990) [hereinafter NL&E Act], and the Food and Drug Administration's implementing regulations at issue in this litigation, establish an onerous premarket clearance system for health claims. This system operates to prohibit GMA members from disseminating a wide range of beneficial nutrition and health information to consumers concerning the food products they manufacture. Accordingly, GMA members have a direct and vital interest in this litigation.

STATEMENT

The decision and opinion below in Nutritional Health Alliance v. Shalala, 953 F. Supp. 526 (S.D.N.Y. 1997), largely rejected the plaintiffs' First Amendment challenge to the regulatory framework governing health claims for food, established under the NL&E Act and implementing regulations promulgated by the Food and Drug Administration (FDA). The FDA regulations prohibit food companies from making any health claim in food labeling unless the claim has been expressly approved by FDA and is stated in the manner prescribed by FDA. 21 C.F.R. § 101.14(e)(1); id. § 101.14; id. Pt. 101 Subpt. E.

The process for approval of a health claim is specified in detailed FDA regulations, which require submission of a petition containing an extensive body of data and information supporting the claim. Id. § 101.70. Within

100 days after receipt of the petition, FDA is required to notify the petitioner that the petition will be "filed" for further review, or denied because the petition deviates from prescribed requirements. Id. § 101.70(j)(2). Within 90 days after filing, FDA is required to deny the petition, or publish a proposed regulation to authorize the health claim. Id. § 101.70(j)(3). Within 270 days after publication of the proposal, FDA is required to publish a final regulation authorizing the claim or explaining why the claim will not be authorized.^{1/} Id. § 101.70(j)(4).

In ruling on plaintiffs' First Amendment challenge to the substantive and procedural health claims provisions of the NL&E Act and FDA's regulations, the district court applied the four-pronged test established by the Supreme Court in Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980). In brief, the court held that under the first prong, health claims are not inherently misleading, and are thus protected commercial speech. Nutritional Health Alliance, 953 F. Supp. at 529. Under the second and third prongs, the court held that the substantial governmental interest test was satisfied by the health claim

^{1/} The requirement that FDA publish a final regulation within 270 days was added by FDA in response to the district court's determination that the absence of a deadline for final action by FDA failed to meet the fourth prong of Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980). See Nutritional Health Alliance, 953 F. Supp. at 530-32.

regulatory regime, and that that regime directly advances the government's interests. Id. at 529-30.

In applying Central Hudson's fourth prong, the district court held that the FDA regulations did not burden more speech than was necessary to further the government's legitimate interests. In reaching this conclusion, the court undertook no analysis of the effect of the regulations or the relevant case law, but instead relied solely on a passage from FDA's preamble to the regulations asserting that they apply only to food product labeling and leave open "a broad range of other communication." Id. at 530. Finally, the court found that the absence of a deadline for FDA to take final action on a proposed claim failed to meet Central Hudson's fourth prong. Subsequently, at the court's direction, FDA promulgated the 270-day limitation within which a final action must be taken. With that modification, the court held that in all challenged respects the statutory and regulatory scheme requiring prior approval of health claims on food labels satisfies the Central Hudson standards for government regulation of commercial speech.

ARGUMENT

I. The District Court Erred In Concluding That The Suppression of Truthful, Nonmisleading Health Claims Under The NL&E Act Satisfies First Amendment Requirements For Commercial Speech.

A. The District Court Failed Adequately to Consider The Expansive Scope of Truthful, Nonmisleading Health Claims Suppressed Under the NL&E Act.

Without any apparent effort to consider the actual spectrum of truthful, nonmisleading speech that is suppressed under the NL&E Act and FDA's implementing regulations, the district court erroneously accepted the government's assertion that the restrictions are reasonable, and acceptable under the First Amendment. Nutritional Health Alliance, 953 F. Supp. at 530.

A careful examination of the nature of the speech suppressed by the health claim regulations establishes that the regulatory scheme adopted under the NL&E Act and implementing regulations exists at the expense of important health messages and at significant cost to public health.

1. The NL&E Act Regulations Permit Health Claims Only In Narrow Circumstances.

The NL&E Act prohibits all health claims except those specifically approved by FDA regulation. 21 U.S.C. § 343(r)(3)(A). The spectrum of claims subject to this premarket approval requirement include all claims "characteriz[ing] the relationship of any nutrient . . . to a disease or health-related condition . . ." 21 U.S.C.

§ 343(r)(1)(B). This requirement applies to both conventional foods and dietary supplements.^{2/}

FDA is authorized to issue a regulation approving a health claim:

"only if the [agency] determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."

Id. § 343(r)(3)(B)(i).

While these provisions establish a premarket clearance procedure for any "claim" characterizing the relationship between a "nutrient" and a "disease or health-related condition," FDA has interpreted these provisions expansively to broaden the scope of claims subject to the premarket clearance procedure, and sharply narrow the circumstances in which a claim may be approved. FDA defined

^{2/} The amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made under the Dietary Supplement Health and Education Act of 1994, Pub. L. 103-417, 108 Stat. 4325 (1994) [hereinafter DSH&E Act], made no change to the health claim provisions with respect to dietary supplements. Section 403(r)(6), which was adopted under the DSH&E Act amendments, authorizes substantiated "statements of nutritional support" for dietary supplements, that is, claims "describ[ing] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characteriz[ing] the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describ[ing] general well-being from consumption of a nutrient or dietary ingredient." Health claims for dietary supplements remain subject to section 403(r)(3) requirements. 21 U.S.C. § 343(r)(3).

the scope of claims subject to the premarket clearance requirement broadly to include all statements, symbols, and other forms of communication that expressly or impliedly associate a food or food component to an improvement in health. 21 C.F.R. § 101.14(a)(1), (2), (6).

There is no statutory definition of "claim" which requires this expansive result. The health claim provisions could have been interpreted much more narrowly, to apply only to statements in which manufacturers independently "characterize" the relationship between a nutrient and a disease or health-related condition. Such an approach would have permitted manufacturers to make factual statements about scientific research or the recommendations and findings of authoritative scientific bodies without subjecting these statements to FDA approval. Under this approach, such factual statements would be regulated under the antideception provisions of the FD&C Act and would be authorized provided they were stated in a truthful, nonmisleading manner, and were substantiated by appropriate scientific evidence. 21 U.S.C. §§ 321(n), 343(a).

At the same time, FDA dramatically narrowed the circumstances for health claim approval. FDA could have issued regulations categorically approving all truthful, factual statements describing the state of the scientific evidence, or the conclusions and recommendations of expert scientific bodies with respect to diet and disease

relationships. Instead, FDA regulations uniformly require proof that the validity of the diet and disease relationship to which a statement refers be accepted by a virtual consensus of scientists before the statement can be made in food labeling. 21 C.F.R. §§ 101.14(c) & 101.70(f); 58 Fed. Reg. 2,478 (Jan. 6, 1993); 56 Fed. Reg. 60,537, 60,547 (Nov. 27, 1991).

FDA regulations also specify a health claim petition procedure by which the required proof must be submitted to the agency. 21 C.F.R. § 101.70. The specific information that must be included in a petition extends far beyond that needed to establish that the claim is truthful and nonmisleading in view of the body of relevant scientific evidence. Rather, petitioners are required to establish that the diet and disease relationship to which the claim refers is considered scientifically "valid" by a virtual consensus of scientists, and to provide a justification of the "public health benefit" that will result if the claim is authorized by FDA. Id. The onerous nature of these requirements has had a substantial chilling effect on health claims. Only five petitions seeking approval of new health claims for food have been submitted to the agency in the seven years since the NL&E Act was adopted.^{3/}

^{3/} The five health claim petitions considered by FDA were submitted by the National Association of Chewing Gum Manufacturers, Inc. (FDA Dkt. No. 95P-0003) (sugar alcohols/dental caries), Quaker Oats Company (FDA Dkt. No. 95P-0197) (oat products/coronary heart disease), the International Dairy

2. The NL&E Act Regulations Ban Truthful, Nonmisleading Qualified Claims Relating to Scientific Research and the Findings of Expert Scientific Bodies.

FDA's unduly restrictive regulations outlaw the use of all statements describing important new studies, even when qualified to reflect the nature of the scientific evidence relied on. Even the district court decision recognized that such qualified claims can be presented in a truthful, nonmisleading manner, citing the following claim as evidence:

"'A study published in the American Medical Journal reports that Vitamin E supplements may reduce the progression of coronary artery disease. This is not an established fact and is still being studied.'"

Nutritional Health Alliance, 953 F. Supp. at 529 n.13

(citation omitted). Nonetheless, the health claims regulations prohibit all qualified claims. In addition, qualified claims based on the conclusions and recommendations of expert groups like the American Heart Association and the American Cancer Society also are prohibited. Like all other health claims, even quotations of these groups are banned unless approved by FDA.

Foods Association (FDA Dkt. No. 96P-0047) (calcium/hypertension), Kellogg Company (FDA Dkt. No. 96P-0338) (psyllium/coronary heart disease), and Kellogg Company (Kellogg's News Release, June 3, 1997) (wheat bran/cancer).

3. The NL&E Act Regulations Ban Truthful,
Nonmisleading Health Claims That Are Not Stated
As Prescribed by FDA.

In addition, FDA has promulgated regulations prescribing the content of approved health claims and the manner in which they must be stated. "Model health claims" are provided to illustrate how a lawful claim is made. 21 C.F.R. Pt. 101, Subpt. E. For example, current regulations require claims concerning the relationship between calcium intake and osteoporosis to include a variety of specific information. The health claim must

"identify the populations at particular risk for the development of osteoporosis. These populations include white (or the term 'Caucasian') women and Asian women in their bone forming years (approximately 11 to 35 years of age or the phrase 'during teen or early adult years' may be used). The claim may also identify menopausal (or the term 'middle-aged') women, persons with a family history of the disease, and elderly (or 'older') men and women as being at risk[.]"

21 C.F.R. § 101.72(c)(2)(B).

FDA's prescriptive requirements present a substantial obstacle to the use of health claims. The requirements prohibit more streamlined and "user friendly" health claims that are more effective in communicating to consumers.

In addition, FDA's prescriptive requirements present a barrier to claims based on the recommendations of authoritative bodies. For example, although FDA regulations authorize limited health claims concerning the relationship between diet and the risks of cancer and heart disease, these

regulations do not permit manufacturers to quote the conclusions and recommendations of FDA's sister agencies such as the National Cancer Institute and the National Heart Lung Blood Institute with respect to these diet and disease relationships, even though such federal agencies have major responsibility for the nation's health.^{4/} In addition, the regulations do not permit manufacturers to quote the conclusions of such authoritative groups as the American Cancer Society, and the American Heart Association. Only statements meeting the precise requirements of FDA's strict rules are allowed. See id. §§ 101.73, 101.75-101.78. As a result, food manufacturers are prohibited from distributing with a food product any pamphlet or written information that is prepared by authoritative groups, even when these concern diet and disease relationships for which FDA has approved claims.

The effect of the regulatory scheme erected under the NL&E Act is to prohibit food and dietary supplement manufacturers from educating the public concerning many

^{4/} The pending enactment of the Food and Drug Administration Modernization Act of 1997 will bring only limited regulatory relief for health claims, which in no way diminishes the importance of the First Amendment issues presented in this litigation. See 143 Cong. Rec. H10,452 (daily ed. Nov. 9, 1997) (Conference Report on S. 830). Section 303 of the legislation would authorize, under a burdensome premarket notification procedure, limited health claims based on the "authoritative statements" of a small number of qualified official scientific bodies of the Federal government, but it would do nothing to authorize claims based on the statements of other authoritative bodies.

important diet and health matters through the use of truthful, nonmisleading claims.

4. The Suppression of Truthful, Nonmisleading Health Claims Imposes Significant Costs on Public Health.

Several historical examples demonstrate that the suppression of truthful diet and health information occurs only at a significant cost to public health. First, as early as the 1950s, the connection between dietary fat consumption and the risk of heart disease was recognized in the scientific literature. In 1957, a major report to the American Heart Association recommended that the general population limit dietary fat because of its connection to cardiovascular disease risk. Irvine H. Page, et al., Atherosclerosis and the Fat Content of the Diet, 16 Circulation 163, 174-75 (Aug. 1957). Soon afterward, the American Heart Association and American Medical Association began to issue dietary guidance encouraging limitations on dietary fat consumption to reduce heart disease risk. Peter Barton Hutt, Government Regulation of Health Claims in Food Labeling and Advertising, 41 Food Drug Cosm. L. J. 3, 29-31 (1986) [hereinafter Government Regulation of Health Claims].

Although scientific evidence of the relationship between fat intake and heart disease risk continued to mount, labeling claims concerning the relationship were prohibited until 1993. See 21 C.F.R. § 101.75 (authorizing limited health claims concerning the relationship between dietary

saturated fat, cholesterol, and the risk of coronary heart disease). As a result, during the period from 1957 to 1993, millions of Americans were denied important health information through food labeling -- the medium available at the point of purchase, where it can best influence healthful food choices.

Ironically, during this period, FDA offered the same kind of justification for the ban that it offers now -- very simply, that the prevention of disease is a matter that should be left to the experts. In a speech delivered in October 1961, the Deputy Director of FDA's Bureau of Enforcement said, "we believe that the prevention . . . of artery and heart disease is a medical problem for the medical experts."

Government Regulation of Health Claims at 29 (quoting K.L. Milstead, *Food Fads and Nutritional Quackery* from the *Viewpoint of the Food & Drug Administration* 12-13 (Oct. 13, 1961)).

Second, FDA brought regulatory action against Fresh Horizons High Fiber Bread in 1976, to prohibit labeling claims stating that increasing scientific opinion recognized that fiber may help prevent diseases including "heart disease" and "cancer." Government Regulation of Health Claims at 44 (citing FDA Regulatory Letter to ITT Continental Baking Company (Oct. 1, 1976)). In 1993, FDA issued regulations authorizing heart disease and cancer claims for foods that contain fiber. See 21 C.F.R. §§ 101.76, 101.77. In the intervening years, millions of Americans were denied important

information on the health benefits of fiber, which could have encouraged more healthful consumption patterns of fiber-containing foods.

Third, the history of FDA's treatment of health claims for folic acid and neural tube defects highlights the health consequences of suppressing truthful health information. In 1992, the Centers for Disease Control and Prevention (CDC) issued a recommendation that women of childbearing age consume specific amounts of folic acid to reduce the risk of having a pregnancy affected by neural tube birth defects such as spina bifida. Public Health Service, U.S. Dep't of Health and Human Services, Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects, 41 MMWR No. RR-14 (Sept. 11, 1992). The CDC estimated that this recommendation could reduce the number of cases of neural tube defects in the United States by 50 percent. Id. Nonetheless, FDA not only would not permit this information to be included in food labeling, but in January 1993, issued rules specifically banning the claim and rejecting the CDC position. 58 Fed. Reg. 2,606 (Jan. 6, 1993). In response to public criticism, the agency reversed course nine months later and proposed to authorize folic acid and neural tube defect claims. 58 Fed. Reg. 53,254 (Oct. 14, 1993). It was not until March 1996 -- 3½ years later -- that final regulations were issued adopting the CDC position. 61 Fed. Reg. 8,752 (March 5, 1996). As a

result of this delay, millions of at-risk children were born to mothers who were denied this important health information.

These are only three examples that highlight the risk to public health presented by the suppression of truthful health information. Unless the courts find the program of health claims censorship established under the NL&E Act unconstitutional, the magnitude of valuable health information denied to Americans will only grow more extreme as diet and disease research advances.

B. The Suppression of Truthful, Nonmisleading Health Claims Under the NL&E Act Violates the First Amendment.

The First Amendment establishes stringent protections for commercial speech that furthers lawful activity and is truthful and nonmisleading. Any attempt by the government to regulate the content of such speech is prohibited unless it survives the rigorous standard first articulated in Central Hudson. Under this standard, a regulation of commercial speech is prohibited unless the restriction it imposes on speech operates "through means that directly advance" a "substantial governmental interest," Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 638 (1985), and is "not more extensive than is necessary to serve that interest." Central Hudson, 447 U.S. at 557. The strict standards established under Central Hudson have been vigorously applied in the Second Circuit to protect commercial speech. See, e.g., New York Ass'n of Realtors, Inc. v.

Shaffer, 27 F.3d 834, 843 (2nd Cir. 1994), cert. denied, 513 U.S. 1000 (1994) (striking down a prophylactic ban on certain real estate solicitations where there was no evidence that less restrictive measures would be ineffective); International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (striking down prescriptive food labeling requirements).

Since the government is the "party seeking to uphold [the] restriction on commercial speech" in this case, the government must carry the "burden of justifying it" under these standards. Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 71 n.20 (1983). The government's burden "is not slight; the 'free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful.'" Ibanez v. Florida Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 143 (1994) (citation omitted). The government's burden is particularly heavy in the case of broad prophylactic bans on truthful, nonmisleading commercial speech, such as the ban on health claims established under the NL&E Act and implementing regulations. "The First Amendment directs [the courts] to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." 44 Liquormart, Inc. v. Rhode Island, 116 S. Ct. 1495, 1508 (1996).

Moreover, the government's conclusions concerning the constitutionality of the law in this case are entitled to no deference by this court because "courts, not agencies, are expert on the First Amendment." Porter v. Califano, 592 F.2d 770, 780 n.15 (5th Cir. 1979). This court must exercise "independent judgment" in evaluating First Amendment claims. Sable Communication, Inc. v. FCC, 492 U.S. 115, 129 (1989).

The government cannot carry its burden to show that the suppression of truthful, nonmisleading health claims meets the rigorous standards of the Central Hudson test. Accordingly, the NL&E Act's regulatory scheme for health claims is prohibited by the First Amendment.

1. The Government Cannot Establish That The Suppression of Truthful, Nonmisleading Health Claims Directly Advances Governmental Interests.

For the suppression of truthful, nonmisleading health claims under the NL&E Act to withstand constitutional scrutiny, it must "directly" advance the asserted governmental interest, Central Hudson, 447 U.S. at 564, and there must be an "immediate connection" between the actual suppression of speech and the asserted interest. Id. at 557. Regulations that restrict the content of commercial speech are prohibited if they "provide[] only ineffective or remote support for the government's purpose." Edenfield v. Fane, 507 U.S. 761, 770 (1993). The government cannot establish the direct connection between its interest and the regulatory device it has chosen through "mere speculation or conjecture," id., but instead

observed that "bans against truthful, nonmisleading commercial speech . . . usually rest solely on the offensive notion that consumers will respond 'irrationally' to the truth." 44 Liquormart, Inc. v. Rhode Island, 116 S. Ct. 1495 (1996). The Court has repeatedly questioned such attempts at control of consumer behavior, subjecting regulations of truthful commercial speech to searching First Amendment scrutiny. Id. at 1508. "The Court . . . [has] resolved beyond all doubt that a strict standard of review applies to suppression of commercial information, where the purpose of the restraint is to influence behavior by depriving citizens of information." Central Hudson, 447 U.S. at 577 (Blackmun, J., concurring in judgment).

In Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976), the Court struck down a law which prohibited certain price-based advertising of prescription drugs, and which was aimed at protecting public health by discouraging consumers from choosing pharmacies based only on the drug prices offered. The Court held that this attempt to promote public health indirectly through the suppression of truthful commercial speech was unconstitutional because it did not "directly" advance the government's interests. Id. at 769. On the same grounds, the Court held that a law which prohibited the posting of real estate "for sale" signs was unconstitutional because it did not "directly" serve the government's objective

must "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." Id.; see also Adolph Coors Co. v. Bentsen, 2 F.3d 355, 359 (10th Cir. 1993) aff'd, 514 U.S. 476 (1995) (holding that restrictions failed to advance directly the government interest where there was no actual evidence the speech suppression would avert the alleged harm).

The government cannot establish that its ban on all health claims that are not approved by FDA directly advances the interests it has asserted in promoting public health. While unsupported or misleading claims are entitled to no constitutional protection, the government cannot establish that suppressing truthful, nonmisleading health claims that are not approved by FDA directly serves the governmental interests.

The government evades this issue, arguing that the restrictions should be permitted because they ban "unsubstantiated" and "unsupported" claims. Defendant's Memorandum at 14-15. But being justified in throwing out the bathwater does not justify throwing out the baby too.

It is not enough for the government to argue that consumers should be shielded from truthful claims that have not been approved by FDA as a means of restraining consumers from responding to truthful information concerning diet and disease relationships that have not yet been definitely established as scientifically "valid." The Supreme Court has

of curbing "white flight" from racially integrated neighborhoods. Linmark Assocs., Inc. v. Township of Willingboro, 431 U.S. 85 (1977).

The Court has made clear that such attempts to manipulate consumer behavior by depriving them of truthful information are suspect and must be subjected to a heightened degree of scrutiny:

"There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that [the] . . . information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them. . . . But the choice among these alternative approaches is not ours to make or the [government's]. It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us. . . ."

Virginia State Bd. of Pharmacy, 425 U.S. at 770.

The suppression of truthful, nonmisleading health claims not only fails to promote the government's public health interests, but also is at direct odds with them. Denying consumers valuable health information imposes substantial costs on public health.

By FDA's own admission, the public health benefit produced by health claims regulation relates directly to the degree to which the dissemination of truthful, nonmisleading health information is authorized. In FDA's preamble to the health claim regulations the agency recognized:

"The benefit of these . . . regulations is to provide for new information in the market in the form of health claims that are not misleading. . . . [M]uch of the benefit of the [NL&E Act] will depend on how health claims are regulated. If mostly incorrect claims are prohibited, consumers will benefit from only seeing those claims that are correct. On the other hand, if claims that are likely to be true are removed, this will decrease the total benefits of the [NL&E Act] as consumers will lose valuable information."

56 Fed. Reg. 60,856, 60,869 (Nov. 27, 1991) (emphasis added).

The public health costs of the NL&E Act regulations obviously are extreme. Of the hundreds of valuable health claims that doubtless could be made, FDA has approved only ten for use in food labeling. See 21 C.F.R. Pt. 101, Subpt. E. As a result, consumers are deprived of a wealth of responsible health information through one of the most accessible and effective media around -- food labeling. Faced with this void, consumers turn to other sources of health information, often to their health detriment, including to the proliferation of books and "talk show" appearances by the health hucksters -- health messages which lay entirely beyond the regulator's reach. By dramatically expanding the health information that could be presented in food labeling, FDA could encourage consumers to rely on responsible, regulated messages instead of the unscientific speculations of quacks.

Because the suppression of truthful, nonmisleading health claims under the NL&E Act regulations does not directly

advance the government's interests, the scheme is prohibited under the First Amendment.

2. The Government Cannot Establish That The Health Claims Regulations Are Narrowly Tailored.

While the severe restrictions imposed on health claims unquestionably deter unsupported or misleading claims, the government cannot establish that the broad prophylactic ban on health claims unapproved by FDA is narrowly tailored to be "no more extensive than necessary" to prevent deception, as required by the First Amendment. Central Hudson, 447 U.S. at 569-70. Under this standard, regulations which "burden substantially more speech than necessary" are unconstitutional. United States v. Edge Broad. Co., 509 U.S. 418, 430 (1993). In discussing Central Hudson's narrow tailoring requirement, the Court has emphasized that "if there are numerous and obvious less burdensome alternatives to the restriction on commercial speech, that is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable." City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 417 n.13 (1993).

Where the Court has readily found less burdensome regulatory alternatives available, it has struck down regulations of commercial speech as overbroad. On this ground, in Discovery Network, the Court held that a policy aimed at promoting public safety and esthetics was unconstitutional insofar as it banned newsracks containing commercial advertising. The Court noted that the government

had failed to consider the alternatives of regulating the size, shape, appearance, or number of newsracks, instead of banning newsracks entirely. Id. at 417.

In Rubin v. Coors Brewing Co., 514 U.S. 476 (1995), the Supreme Court held that a federal law prohibiting beer labels from displaying alcohol content was unconstitutional because "the Government's regulation of speech [was] not sufficiently tailored to its goal" of discouraging "strength wars." Id. at 544. The Court observed, in particular, that regulatory alternatives were readily available that "could advance the Government's asserted interest in a manner less intrusive to [the manufacturer's] First Amendment rights." Id.

In New York State Association of Realtors v. Shaffer, 27 F.3d 834 (2d Cir.) cert. denied, 513 U.S. 1000 (1994), the Second Circuit Court of Appeals struck down a ban on real estate solicitations in certain geographic areas where the government had failed to establish that the ban was narrowly tailored to its interest in combating "blockbusting," a solicitation practice that preys upon racial fears to stimulate real estate sales in transitional neighborhoods. The court emphasized that the government had failed to gather empirical evidence concerning the effectiveness of alternative regulatory approaches, and thus had not "carefully calculated" the "cost" of the regulation. Id. at 844.

"Particularly troubling in this case is the Secretary's failure to determine

empiracally [sic] whether less restrictive measures, such as the implementation of cease and desist orders, would provide an alternative means for effectively combating the level of blockbusting evidenced by the record in this case. The Secretary, moreover, offers no evidence of any kind that this type of narrower, resident activated measure, a measure that was in effect prior to the issuance of the solicitation ban, is an ineffective means for combating the individual incidents of blockbusting. . . . In the absence of such evidence, we find it difficult to accept the Secretary's position that a community wide, comprehensive ban on all real estate solicitations, regardless of the otherwise proper content of those solicitations, as opposed to the issuance and enforcement of the cease and desist orders on an individualized basis, is a reasonably tailored means for eliminating the harm of blockbusting as portrayed by this record."

Id.

On similar grounds, in Hornell Brewing Co. v. Brady, 819 F. Supp. 1227 (E.D.N.Y. 1993), the federal district court struck down a ban on the "Crazy Horse" name on alcoholic beverages. The court rejected the government's assertion that the ban was needed to help prevent alcohol abuse by Native Americans, holding that the restriction failed to satisfy Central Hudson's narrow tailoring requirement. Id. at 1229. The court found that the government had failed adequately to consider obvious alternatives to the suppression of speech, including alcohol education programs designed for Native Americans. The court said that, in view of the "obvious alternatives available that do not hinder speech in any way,

or hinder it far less, the statute is not, by any means, a reasonable fit." Id.

The less burdensome alternatives to the total ban on claims not specifically approved by FDA which is established under the NL&E Act and FDA implementing regulations are numerous and obvious. The Federal Trade Commission (FTC), all fifty states, and the District of Columbia effectively regulate health claims in food advertising under statutes prohibiting false and deceptive advertising. These laws require marketers to state claims in a truthful and nondeceptive manner, and to substantiate claims before they are made. See Kenneth A. Plevan & Miriam L. Siroky, Advertising Compliance Handbook 288-312 (2d ed. 1991). Government preclearance of claims is not required.

Under the FTC Enforcement Policy Statement on Food Advertising, health claims may be made in food advertising when substantiation establishes a "reasonable basis" for the claim. 59 Fed. Reg. 28,388 (June 1, 1994). This standard applies equally to all health claims, regardless of whether they are approved by FDA. The FTC Policy makes clear that health claims that are stated broadly, and do not disclose explicitly the level of scientific support for the claim, are permitted provided there is "significant scientific agreement" that the body of relevant evidence supports the claim. No government preclearance of the claim is required. Id. at 28,392. Claims based on more limited scientific evidence also

are permitted, provided they are "expressly qualified to convey clearly and fully the extent of the scientific support" for the claim. Id. at 28,394.

The FTC policy sets out "safe harbors" to guide marketers in constructing truthful, nonmisleading claims, but establishes no preclearance system for health claims. The FTC polices claims on a case-by-case basis, investigating the substantiation of questionable claims and initiating enforcement actions when substantiation is deficient.

The FTC policy is an obvious regulatory alternative to the ban on claims imposed under the NL&E Act and implementing regulations. Because the FTC policy imposes no restriction on truthful, nonmisleading claims that are properly substantiated, it imposes a much lighter burden on truthful speech than does FDA's regulations.

FDA has offered no empirical evidence establishing that the FTC health claims policy would be ineffective to regulate health claims in labeling. To the contrary, the FTC policy is similar to the one FDA has developed to implement section 403(a) of the FD&C Act, 21 U.S.C. § 343(a), which imposes a blanket prohibition on false or misleading labeling. Although the provision has applied to food labeling since 1938, the agency never has argued that FDA preclearance of food labels or a ban on all unapproved claims should be imposed to effectively protect consumers from deception.

In the face of the obvious, less burdensome alternatives to the ban on unapproved and unqualified claims, the government cannot establish that the regulatory scheme for health claims in labeling satisfies the narrow-tailoring standard of Central Hudson. The scheme thus is prohibited under the First Amendment.

II. The District Court Erred In Holding That The First Amendment Requirements For Commercial Speech Are Satisfied By The Prohibition Of Health Claims On Food Labels Pending Exhaustion Of A Protracted And Burdensome Prior Approval Procedure.

In applying the second and third prongs of the Central Hudson test, the district court held that the health claims approval regime of the NL&E Act and FDA implementing regulations directly advances a substantial government interest. Nutritional Health Alliance, 953 F. Supp. at 529-30.^{5/} The court also held that under the Central Hudson fourth prong, the regulation does not burden more speech than necessary to further FDA's legitimate interests, but that the absence of "any deadline whatsoever for the final authorization of a proposed health claim . . . fails to meet Central Hudson's fourth prong . . ." It held that the First Amendment does not permit the FDA to prohibit this speech for an indefinite period, and that the lack of a firm deadline for

^{5/} The court rejected the government's contention that health claims are inherently misleading and can thus be prohibited under the first prong of the Central Hudson test. Id. at 529.

the publication of a final regulation is not a "reasonable fit." Id. at 530.

FDA was directed to establish a reasonable deadline and to submit it to the court for approval. Id. at 532. This process resulted in FDA's establishment and the court's eventual approval^{6/} of a requirement that FDA publish a final regulation approving or denying a health claim within 270 days after it is published as a proposal, with a provision for the agency to extend the deadline for up to an additional 180 days. 62 Fed. Reg. 28,230, 28,232 (May 22, 1997). The district court's approval of these nonstatutory deadlines thus assures that a party submitting a health claim petition cannot expect final FDA action to approve or deny the claim until at least 460 days, and as long as 640 days, have elapsed from the time that a petition is submitted.^{7/}

^{6/} See Nutritional Health Alliance v. Shalala, No. 95-CV-4950 (RO) (S.D.N.Y. Aug. 1, 1997) (Memorandum and Order approving 270-day time frame as "not beyond an appropriate range").

^{7/} Under § 403(r)(4) (21 U.S.C. § 343(r)(4)) FDA must decide whether to file a petition for review within 100 days and whether to publish the claim as a proposal within an additional 90 days. The 270-day deadline for taking final action on a proposal with possible extensions of up to 180 days thus gives FDA a total of between 460 and 640 days from the time a petition is submitted for reaching a final decision.

Section 302(3) of the Food and Drug Administration Modernization Act of 1997, 143 Cong. Rec. H10,452 (daily ed. Nov. 9, 1997) (Conference Report on S. 830), will amend section 403(r)(4)(A)(i) of the FDCA (21 U.S.C. 343(r)(4)(A)(i)), to provide that if FDA issues a proposed regulation to approve a health claim, final action must be completed within 540 days of the date the petition is received

If the claim is denied, the burden is on the proponent of the claim to seek judicial review of the agency's final action. Throughout this process and pending a decision by the reviewing court, the claim is prohibited, and any attempt to distribute in commerce a food bearing the claim will subject the company to criminal prosecution. See 58 Fed. Reg. at 2,534; see also 21 U.S.C. § 343(r) (3) (A).

This burdensome and extended prior approval process established by the NL&E Act and the FDA, and sanctioned by the court below, is totally at odds with the First Amendment principles governing commercial speech as developed by the Supreme Court in a large body of recent case law. The Court has repeatedly required that governmental restraints on commercial speech be narrowly tailored to achieve the asserted governmental interest. See, e.g., Central Hudson, 447 U.S. at 571. In Central Hudson, the Court invalidated a State Commission order banning all promotional advertising by an electric utility, which the Commission sought to justify on energy conservation grounds. In suggesting more limited regulatory alternatives to a total ban on advertising, the Court added in a footnote:

by FDA. In view of FDA's past record in complying with statutory deadlines, it is likely that final action will seldom, if ever, be completed in advance of this new 540-day deadline. The 1997 amendments do not alter the fact that a company filing a health claim petition will be prohibited from making the claim during the pendency of FDA review and any subsequent judicial review.

"The Commission also might consider a system of previewing advertising campaigns to ensure that they will not defeat conservation policy We have observed that commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it. Virginia Pharmacy Board v. Virginia Citizens Consumer Council, 425 U.S. at 771-72 n.24. And in other areas of speech regulation, such as obscenity, we have recognized that a pre-screening arrangement can pass constitutional muster if it includes adequate procedural safeguards. Freedman v. Maryland, 380 U.S. 51 (1965)."

447 U.S. at 571 n.13.

The prior restraint doctrine in relation to commercial speech has not otherwise been authoritatively addressed by the Supreme Court. In at least two more recent cases, however, the Court has suggested that filing copies of the advertising at issue with the State would give it "ample opportunity to supervise mailings and penalize actual abuses," and would be a "far less restrictive and more precise means" of regulating advertising abuses than a total ban on the category of advertising in question. Shapero v. Kentucky Bar Ass'n, 486 U.S. 466, 476 (1988).

Similarly, in In re R.M.J., 455 U.S. 191, 206 (1982), the Court held that a total ban on promotional mailings by lawyers to prevent misleading the public did not meet First Amendment requirements for commercial speech. The Court suggested that "by requiring a filing with [the State] . . . of a copy of all general mailings, the State may be able to exercise reasonable supervision over such mailings." Such an approach would permit the state to exercise its "authority

to regulate advertising that is inherently misleading or that has proved to be misleading in practice." Id. at 206-07. At the same time, this approach would be consistent with the Court's holding that:

"although the States may regulate commercial speech, the First and Fourteenth Amendments require that they do so with care and in a manner no more extensive than reasonably necessary to further substantial interests. The absolute prohibition on appellant's speech, in the absence of a finding that his speech was misleading, does not meet these requirements."

Id. at 207.

The prefiling systems suggested by the Court in both Shapero and In re R.M.J. as acceptable and less restrictive means for preventing deceptive advertising would enable the state to review the advertising or promotional material and take appropriate judicial action against false or deceptive claims. There is no indication in either case, however, that the Court had in mind a system that would preclude use of the advertising material pending administrative and judicial review. In contrast, the health claim approval procedures sanctioned by the court below prohibit companies from making any claim in food labeling, pending preparation and submission of an elaborate petition to FDA, FDA review of the petition in a protracted administrative process of up to 640 days (nearly two years), and completion of any subsequent judicial

review.^{8/} This extended ban on health claims on food labeling is squarely at odds with the Supreme Court's repeated insistence that government regulation of commercial speech be "no more extensive than reasonably necessary to further substantial interests." In re R.M.J., 455 U.S. at 207.

The Supreme Court's brief discussion of commercial speech and the prior restraint doctrine in the Central Hudson footnote^{9/} of course preceded the more specific statements in Shapero and In re R.M.J. that prefiling procedures are an acceptable regulatory approach to the regulation of advertising. In view of the Supreme Court's determination in these later cases that premarket notification of advertising, without a governmental preclearance requirement, is an effective and acceptable means for regulation of commercial speech, it must be concluded that a more restrictive approach involving any prohibition of advertising pending government approval would fail to satisfy the narrow tailoring

^{8/} The pending legislation that will amend, inter alia, the health claims provisions of the FD&C Act, see supra note 7, authorizes in section 303 a limited premarket notification procedure for claims based on authoritative statements of a small number of qualified official scientific bodies of the federal government. Such claims can be made 120 days after submission of a notification, but another amendment in section 301 of the bill to section 403(r) of the FD&C Act (21 U.S.C. § 343(r)) authorizes FDA to issue an immediately effective regulation at any time banning the claim described in the premarket notification. Under the First Amendment analysis presented in this brief, it is clear that such an administrative ban is no less vulnerable to constitutional challenge than the petition procedure.

^{9/} See supra at 29-30.

requirement. Unquestionably, the FDA prior approval process for health claims is far more restrictive than the procedures expressly found to be acceptable in Shapero and In re R.M.J.

Under this analysis, the somewhat more restrictive procedural safeguards for prescreening films for obscene material established in Freedman v. Maryland, and referenced by the Court in Central Hudson, may be regarded as more restrictive than necessary in the context of government regulation of commercial speech designed to identify and take action against false and misleading labeling and advertising.

It is clear, in any event, that the FDA health claim approval procedures sanctioned by the court below fall far short of satisfying even the procedural safeguards described by the Court in Freedman. Under Freedman, the burden of proving that the speech in question is unprotected expression rests on the government. Second, while the state may require advance submission of films, the exhibitor must be authoritatively assured that the censor will "within a specified brief period, either issue the license or go to court to restrain showing the film." Third, any restraint imposed in advance of judicial resolution must be limited to "the shortest fixed period comparable with sound judicial resolution." Freedman, 380 U.S. at 58-59.

The FDA health claims approval regime very clearly fails to meet the procedural safeguards established in Freedman. The protracted FDA review process is in no sense

consistent with the holding in Freedman that the government must act within a "brief period" either to approve the film or itself seek judicial action to prevent the film from showing. 380 U.S. at 58-59. In contrast, under the NL&E Act procedure, a company whose proposed health claim has been ultimately disapproved by the FDA -- after an extended period that is far from "brief" -- has the burden of going to court if it wishes to challenge that decision.

Finally, it is clear that under any filing or prescreening procedure for health claims that is deemed to meet the First Amendment requirements for regulation of commercial speech, the FDA would be free at any time to go to court to challenge a health claim on a food label that the agency regarded as failing to meet the applicable statutory standards. This is of course the procedure under which FDA operates with respect to all non-health related labeling claims for food products, under which the claim cannot be banned until a judicial decision has been reached. 21 U.S.C. §§ 332-334 and 343. Similarly, the FTC administers statutory prohibitions against false and deceptive advertising on a case-by-case basis by initiating administrative proceedings that cannot operate to prohibit an advertising claim in the absence of an authoritative judicial determination.^{10/}

These long-established FDA and FTC procedures for the prevention of false and misleading labeling and

^{10/} See supra at 25.

advertising demonstrate obvious and effective regulatory alternatives to FDA's protracted and burdensome prior approval scheme for health claims. Quite clearly, that scheme fails to satisfy the requirement under Central Hudson and numerous other Supreme Court cases that government regulation of commercial speech must be narrowly tailored in order to meet the requirements of the First Amendment.

CONCLUSION

The requirements and procedures for the approval of health claims in food product labeling established by the NL&E Act and FDA regulations fail to satisfy First Amendment requirements for government regulation of commercial speech. First, the Act and regulations impermissibly prohibit a broad range of truthful, nonmisleading claims on food labels to the detriment of public health. Second, there are obvious, long-established, and less restrictive regulatory means for the prevention of false and misleading labeling and advertising. This Court should hold that the NL&E Act health claim

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