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DATE OF CORRESPONDENCE: 01/12/04 **DATE INTO FDA:** 01/15/04

TO: TOMMY G THOMPSON, SECRETARY, HEALTH AND HUMAN SERVICES

FROM: MAUREEN STOREY, VIRGINIA TECH

SYNOPSIS: SWIFT D/R - SUBMITS COMMNETS ON THE WORLD HEALTH ORGANIZATION'S (WHO) PROPOSED GLOBAL STRATEGY ON DIET, PHYSICAL ACTIVITY, AND HEALTH FOR AN INTEGRATED APPROACH TO THE PREVENTION OF NONCOMMUNICABLE DISEASES.

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COORDINATION: HFG-1
HFS-1

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO		ACTION	DUE DATE
HF-40	SLIVAC	PREPARE DIRECT REPLY	01/28/04

HFG-1 NECESSARY ACTION
REMARKS: PLEASE COORDINATE WITH €IF-40.

HFS-1 NECESSARY ACTION
REMARKS: PLEASE COORDINATE WITH HF-40.

Secretary's Correspondence

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

From:	Maureen L. Storey	*OS#:*	**011420040051**
Organization:	Virginia Tech	*Date on Letter:*	**1/12/04**
City/State:	Alexandria VA	*Date Received:*	**1/14/04**
On Behalf Of:		*Type:*	General Public

Subject: Fotwards comments on the World Health Organization's proposed global strategy on diet, physical activity and heath for an integrated approach to the prevention of noncommunicable diseases.

Assigned to:	FDA	*Dep.ES:*	Dick Eisinger
PC:	Teresa Floridi	*Date Assigned:*	**1/14/04**
Action Required:	Direct Reply	*Date Reassigned:*	
		Reply Due Date:	**1/28/04**

Info Copies To: Floridi, Teresa (HHS/OS); SWIFT, OGHA; SWIFT, OPHS

Interim (YIN): No *Date Interim Sent:*

Comments:

File Index: **PO-4-6** *c c c:* Elaine Gross

01-15-04A10:24 KCVD

04-306

Virginia Tech
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An FAO Center of Excellence for Food and Nutrition Policy

January **12,2004**

The Honorable Tommy G. Thompson
Secretary, Department of Health and Human Services
200 Independence Avenue, SW
Room **615-F**
Washington, D.C. **20201**

Dear Secretary Thompson:

The Center for Food and Nutrition Policy at Virginia Tech (CFNP) respectfully submits the following comments to the U.S. delegation with regard to the World Health Organization's proposed global strategy on diet, physical activity, and health for an integrated approach to the prevention of noncommunicable diseases.

CFNP generally agrees with the principles that guided the development of the global strategy. These guiding principles are:

- "Stronger evidence for policy—to draw together existing scientific information on the relationship between diet, physical activity, and noncommunicable diseases and knowledge about interventions;
- Advocacy for *policy change*—to inform decision-makers and stakeholders of the problems, determinants, interventions and policy needs;
- Stakeholder *involvement*—to agree on the roles of stakeholders in implementing a global strategy;
- Strategic *framework* for action—to propose appropriately tailored policies and interventions for countries."

CFNP Strongly Opposes Using the WHO Technical Report 916 as a Basis for Developing Any Global/National Strategy and Any Subsequent Action Plans.

The rationale for the CFNP's opposition is noted in the supporting document detailed below.

In a letter dated May 9,2002, and addressed to Dr. Pekka Puska, then Director of Noncommunicable Disease Prevention and Health Promotion at WHO (Appendix 1), CFNP, along with several other prominent scientists, urged WHO to:

1) "withdraw the current version of this draft report because it fails to address the other key factors in preventing obesity—physical activity and fitness;

2) re-examine the policy recommendation that imposes food taxes that are likely to and can be ignored by the rich and middle-class, while having a disparate impact that further impoverishes the poor;

3) re-submit a revised report to a balanced, independent panel of referees, experts in nutrition, physical activity, economics, and food production."

The WHO revised the report somewhat, but failed to correct the unacceptably biased interpretations of literature.

WHO Technical Report 916 Must Not Serve as a Basis for National Guidelines

The first guiding principle—stronger evidence for policy—is the most important one for developing efficient, effective, and targeted policy on which to base national guidelines by Member states. The review of the current science on which policy is based must be comprehensive, and the interpretations of the science must be transparent. CFNP therefore is concerned about the heavy reliance on the WHO's technical report 916 in developing a global strategy. Any strategy based on limited science is flawed and leads to country-specific action plans that fail to address the most critical nutrition and health problems in these countries. Moreover, CFNP strongly opposes the suggestion that the report of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Disease is to serve as a basis for establishing national guidelines.[1]

The 916 report should not serve as a basis for national guidelines because it is scientifically weak and transparently biased in selecting review articles, book chapters, and entire books that support a pre-established political position that do

[1] World Health Organization, Executive Board, 113th Session, Provisional agenda item 3.7, EB 113/44 Add.1, November 27, 2003. p.10, paragraph 34, sub-paragraph 2, sentence 1.

not critically examine the science. This is particularly apparent in the two chapters on weight gain/obesity and osteoporosis. Nearly half of the references used to substantiate certain statements made in the obesity section are reviews, books, book chapters, proceedings, and even an editorial. The weakness of the scientific evaluation is also very obvious in the osteoporosis chapter of the 916 report, which cites a mere 18 references out of potentially hundreds of relevant, peer-reviewed papers.

CFNP is troubled by the extreme biases apparent in the 916 report. These biases are represented as if they had been scientifically validated by the "strength of the evidence." For example, in Table 7 of the 916 report,[2] WHO states that there is ***probable*** evidence that heavy marketing of energy-dense foods and fast-food outlets increases the risk of weight gain and obesity. In the same table, however, the report suggests that there is ***possible*** evidence that large portion sizes and a high proportion of food prepared outside the home in developed countries increase this risk. These categorizations are inconsistent and promote conjecture not supported by scientific evaluation. To place these opinions in a "Strength of Evidence" table gives undeserved credibility to untested hypotheses and unscientific, political biases.

The draft of the WHO Technical Report 916 introduced the concept that lifestyle habits — including eating and physical activity patterns — are "like an infectious disease."

> ***"Sometimes chronic diseases are considered communicable at the risk factor level. Modem dietary patterns and physical activity patterns are risk behaviours that travel across countries and are transferable from one population to another like an infectious disease, affecting disease patterns globally."*** Draft of the WHO Technical Report Series 916, Section 2, Background, p. 4.

Diabetes, osteoporosis, hypertension, and other chronic disease are not infectious, like Severe Acute Respiratory Syndrome (SARS) or tuberculosis, nor should they be editorialized as such. This editorial analogy must **not** serve as the basis for a concept presented in the 916 report. It is misleading to non-scientists and others who must rely on the report to develop country-specific policies.

While the final WHO Technical Report 916 avoids the analogy of infectious disease, it introduces the term ***"food-related infectious diseases"*** (section ***2.3,*** pp. 9-10). The meaning of this term in the final report is unclear, but may be intended to communicate the inappropriate concept of the epidemiological triad

[2] WHO Technical Report 916, ***Diet, Nutrition and Prevention of Chronic Diseases,*** a Report of a Joint WHO/FAO Expert Consultation, Chapter 5.2, Section 5.2.4, p. 63.

(host-vector-environment) for communicable, infectious diseases as introduced in the draft report. If the WHO is implying that undernourished individuals are more susceptible to contracting infectious diseases, then the proper, more descriptive, and accurate term is ***"hunger-relatedinfectious disease"*** or ***"lack-of-food-related infectious disease."***

A Thorough Scientific Review on Obesity Should Be Conducted in a Transparent Process

CFNP recommends that global strategies be based on comprehensive, global reviews of the current science on obesity and its links to chronic diseases. Moreover, the process used for such reviews must be conducted in a transparent and rigorous manner that can stand up to external scrutiny. For example, the U.S. Food and Drug Administration (FDA) recently proposed a process to evaluate the scientific literature for the purpose of allowing qualified health claims on food packages.[3] The process developed by the FDA is thoughtful and constructive, and it can serve as a template for conducting a scientific review of the obesity literature.

On October 8, 2003, the U.S. Food and Drug Administration published a request for comments on obesity issues in the ***Federal Register***.[4] CFNP submitted comments to FDA noting that multiple factors are associated with increased risk of obesity. The following are excerpts from those comments that are relevant to the WHO strategy. Please refer to Appendix I for the complete comments:

> "On July 10, 2003, FDA issued industry guidance and interim procedures for makin qualified health claims on human foods and dietary supplements! In like fashion, the Center for Food and Nutrition Policy urges FDA to establish a similar rigorous framework for evaluating the 'weight of the evidence' in establishing regulations, guidance, educational campaigns, or research agendas that are within FDA's scope of responsibility in addressing the issue of overweight and obesity in the American population.
>
> Few reasonable scientists disagree that excess body weight is the result of an imbalance between energy (calories) consumed and energy expended. But there are many factors—non-modifiable and modifiable—that contribute to one's risk of becoming overweight. Non-modifiable risk factors for overweight include genetics (that may include race/ethnicity), age, and gender. Modifiable risk

[3] http://www.cfsan.fda.gov/~dms/hclmgui3.html#intro
[4] Federal Register: Notices. October 8, 2003, Volume 68, Number 195, pages 58117-58118.
[5] http://www.cfsan.fda.gov/~dms/hclmgui3.html#intro

factors include lifestyle habits, such as levels of physical activity at work and during leisure time, sedentary behaviors, and diet."

CFNP therefore suggests that the U.S. delegation urge WHO, in equal partnership with the Food and Agriculture Organization (FAO) and in cooperation with other prominent scientific bodies around the world, to conduct a rigorous review of the research in a transparent, objective manner such as the process outlined by the FDA—or one similar to it—for reviewing the weight of the evidence on obesity and its link to chronic diseases.

Many Factors Must Be Considered in Preventinn Overweight and Obesity

CFNP agrees that healthy body weight is important to reducing the risk of age-related chronic diseases, but there are many factors other than diet and physical activity that play even larger roles in determining an individual's risk of becoming overweight. These factors are explored thoroughly by Storey and her colleagues in a recent paper on demographic and lifestyle factors involved in determining body mass index among children and adolescents. In this paper, the authors examined the relative importance of non-modifiable risk factors—age, gender, and race/ethnicity—and modifiable lifestyle factors—physical activity, sedentary behavior, and diet—to development of overweight and obesity among children and adolescents.[6] The risk factors that cannot be controlled were more predictive of an individual's body mass index (BMI) than sedentary behavior (as measured by hours of television or video watching) and dietary components. Moreover, the number of hours of television watched was positively linked to higher BMI while dietary components, including added sugars, were not consistently associated with BMI.

Several scientists have proffered the notion of a global ***nutrition transition*** that is leading to greater incidence of overweight and obesity among children and adults. Yet there is little acknowledgement about the effect of the ***physical activity transition,*** which is equally as powerful in promoting weight gain on a population basis. As noted by the economists Philipson and Lakdawalla,[7] the transition from occupations requiring heavy physical labor to those that are sedentary has a profound effect on body weight. These economists suggest that 60 percent of the extra weight put on by Americans may be due to the decline in the physical demands of work brought about by the use of computers. Years ago, work was physically demanding, and the average American was paid to be

[6] Storey ML, Forshee RA, Weaver AR, Sansalone WR. Demographic and lifestyle factors associated with body mass index among children and adolescents. *J Intl* Food *Sci Nutr* **2003;54**: 491-503.

[7] Lakdawalla D and Philipson T. The growth of obesity and technological change: a theoretical and empirical examination. National Bureau of Economic Research Working Paper 8946, May 2002.

physically active. **Now** the opposite is true. Few people have physically demanding jobs and are paid to be sedentary. When they exercise, they very often pay to do so.

Strategies to stem the obesity epidemic must be based on science and credible scientific hypotheses that consider the multiple factors involved. The Partnership to Promote Healthy Eating and Active Living (PPHEAL)—a non-profit coalition of public and private organizations-examined the many factors related to eating healthfully and being physically active. In 2000, PPHEAL, led by Dr. James Hill from the University of Colorado Health Sciences Center and supported by industry, convened a summit to examine these factors at the individual level and their interactions with the environment. The useful framework developed at that summit is shown in Appendix **3** and can be accessed at the website: www.ppheal.org.

This framework shows multiple leverage points that influence individual behavior. Beginning with the individual psycho-biological core, cultural and social pressure points also affect eating and physical activity habits. Environmental influences, as well as primary and secondary leverage points, are further overlays that affect lifestyle.[8] Implicit within the social and economic factors noted in this framework are additional elements that may play a role in individual behavior. These additional elements can include life events such as marriage, birth of a child, death of a parent or spouse, and so forth. These life events can affect how one interacts with and responds to his or her environment. For example, the death of a spouse or parent may trigger changes in an individual's eating behaviors and physical activity levels.

The PPHEAL illustration clearly suggests that changing the behavior of an individual or a population is not as simple as taxing "undesirable" food(s) or restricting advertising. CFNP strongly recommends that governments reject taxation of so-called "undesirable" food(s) because these regressive taxes will fail to accomplish their goals. Furthermore, CFNP encourages governments to consider the PPHEAL framework as a template for establishing policies that encourage people to eat healthfully and be more physically active.

lu< i Is ital to Preventing unicable Diseases

The WHO draft strategy on diet, physical activity, and health points out the importance of education, communication, and public awareness in the reduction of noncommunicable diseases related to food and nutrition. CFNP agrees to this strategy in principle. The WHO strategy also emphasizes that "...media literacy

[8] Nutrition **Reviews, Vol. 59, March 2001, Number 3** (Part II.)

skills starting in primary schools are critical to countering food fads and misleading dietary advice."[9] CFNP believes it is far more important that children and adults be literate in science and critical thinking skills. Only then can people properly scrutinize, evaluate, and discern the difference between fact and fiction.

In developing countries, basic education in food safety is the highest priority. Clean water and safe food handling/preparation are needed for preventing disease. The highest priority should be to educate people about basic food handling skills, such as washing their hands before preparing food, than expending limited resources on media literacy.

WHO Fails to Address Hunger and Inadequate Nutrient Intake

In the November 27, 2003 Annex to the draft global strategy on diet, physical activity, and health," WHO notes "a profound shift in the balance of the major causes of death and disease is under way in most countries. Globally, the burden of noncommunicable diseases has rapidly increased. In 2001, noncommunicable diseases accounted for almost 60% of the 56.6 million deaths annually and 47% of the global burden of disease." There are approximately 800 million people in the world who suffer from food insecurity, yet in the draft strategy, WHO is encouraging countries to focus their limited resources on those who have more than enough to eat. It is the lack of food and monotonous, nutrient-poor diets that lead to preventable disease and disability, including goiter and mental retardation from iodine deficiency, blindness from vitamin A deficiency, anemia and poor birth outcomes from iron deficiency among many others. In developing countries that have limited resources, highlighting obesity as a public health burden diminishes the greater public health cost of hunger and nutrient insufficiency.

CFNP therefore encourages WHO, in equal partnership with the FAO, to develop a matrix of communicable and noncommunicable diseases that represent the greatest burdens of disease for each of its regions. This will help governments understand which diseases should be their highest priorities, and, therefore, which diseases will require the greatest government resources to combat.

Food Taxes Are Unlikely to Change Behavior and Are Likely to Have Negative Consequences

CFNP strongly disagrees with WHO's encouragement of the governments of Member states "to use tax policy and other fiscal measures in a manner that

[9] World Health Organization, Executive Board, 113th Session, Provisional agenda item 3.7, EB 113/44 Add.1, November 27, 2003. p.11, paragraph 35, sub-paragraph 1, sentence 6.
[10] World Health Organization, Executive Board, 113th Session, Annex to EB 113/44.

promotes health and is fiscally sustainable."[11] There is no credible evidence that public policies designed to increase the cost of food through regressive food taxes will positively influence individual food choices in any manner that will affect overall health. Taxes on food only make food more expensive and decrease disposable income that could be used for other necessities. Indeed, these taxes primarily increase the food costs of those people who can least afford higher prices. This forces poor people to spend a disproportionately higher amount of their income on food. In effect, the WHO is promoting making poor people even poorer by increasing the cost of food through regressive food taxes.

WHO also suggests other fiscal tools, such as adjusting agricultural subsidies to cause profound changes in national diets. Agricultural subsidies are multifaceted and have complex impacts on inter-related global economies. Agricultural policies have a great effect an national diets by supporting a productive, robust agricultural sector that feeds its own population as well as many others. But there is no evidence, as the WHO strategy implies, that agricultural policies lead to unhealthy dietary patterns, or that agricultural policies will change population food consumption patterns.

Monitoring, Surveillance, Research, and Evaluation Are Vital to Sound Strategy

CFNP concurs with WHO that substantial investment is needed to monitor, survey, research, and evaluate major risk factors as well as their responsiveness to policy changes and strategies. CFNP urges WHO and government agencies to support longitudinal studies of lifestyle habits, including physical activity and diet. These types of studies are lacking and are especially important in providing valuable data about the root causes of obesity. Moreover, the futility of collecting data that is unanalyzed is obvious. Funding for data analysis must accompany the funding for data collection. The evaluation component of policies and programs often falls victim to budget constraints. Strategies and action plans seldom undergo the careful scrutiny needed to wisely re-invest in successful programs or to eliminate ineffective ones.

Summary of Comments

CFNP urges the U.S. government to:

1. Reject the technical report 916 of the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic

[11] World Health Organization, Executive Board, 113th Session, Provisional agenda item 3.7, EB 113/44 Add.1, November 27, 2003. pp. 11-12, paragraph 36, sentence 5.

Disease as a basis for developing a global strategy for reducing noncommunicable disease risk;

2. Endorse a thorough, objective review of the factors involved in the development of obesity;

3. Encourage educational efforts that increase science and health literacy with population-appropriate priorities;

4. Oppose food taxes as imprudent policies that will fail to positively change individual behavior regarding food choices;

5. Support monitoring, surveillance, research, and evaluation of sound strategies to reduce the risk of noncommunicable food and nutrition-related diseases; and

6. Consider using the framework proposed by the Partnership to Promote Healthy Eating and Active Living shown in Appendix 3 as the basis for a strategy to prevent overweight and obesity.

Respectfully submitted,

Maureen L. Storey

Maureen L. Storey, PhD
Director

att.

Appendix I

May 9, 2002 Letter from the Center for Food and Nutrition Policy at Virginia Tech addressed to Dr. Pekka Puska.

Virginia Tech

VIRGINIA POLYTECHNIC INSTITUTE
AND STATE UNIVERSITY

Center for Food and Nutrition Policy & The Ceres® Forum
An FAO Center of Excellence on Food and Nutrition Policy

1101 King Street, Suite 611
Alexandria, VA 22314
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May 9,2002

Dr. Pekka Puska
Director, Noncommunicable Disease Prevention
and Health Promotion
Noncommunicable Diseases and Mental Health
World Health Organization
CH-1211
Geneva, 27-Switzerland

Dear Dr. Puska:

The Center for Food and Nutrition Policy (CFNP) is an independent, non-profit, center chartered at Virginia Polytechnic Institute and State University. The CFNP mission is to advance rational, science-based food and nutrition policy, and it is recognized as a Center of Excellence on such matters by the Food and Agriculture Organization of the United Nations (FAO). The following represents our views on the draft report Diet, *Nutrition and the Prevention* of *Chronic* Diseases developed by the WHO/FAO expert consultation.

First, the draft report acknowledges that the review does not examine the energy expenditure side of the energy balance equation to any great extent: We believe that this is a serious omission and directly conflicts with at least one earlier report published by FAO and WHO. Indeed, in January 2002, the WHO endorsed physical activity as a major determinant of good health. The 1998 Joint FAO/WHO Report on Carbohydrates in Human Nutrition notes that excess energy consumption will promote body fat accumulation and obesity if energy expenditure is not adjusted to the level needed for daily energy requirements. Policy recommendations that concentrate on only one aspect of the dietary patterns-energy expenditure complex should not be promulgated as an approach to attenuating, and eventually reversing, the global problem of weight gain and obesity.

Second, the draft report stresses the importance of shifting dietary patterns as a significant cause of disability and premature death from noncommunicable diseases (NCDs). It is quite easy to understand why the disease approach exemplified by the *Epidemiological Triad* for infectious or communicable diseases was proposed "for convenience." But when recommendations concentrate solely on food groups or the

dietary aspect, and are coupled with the epidemiological triad, with a focus on the "environment," policy becomes disengaged from scientifically validated approaches. Consequently, recommended actions such as the following bullet points appear to rest on weak evidence and subvert educational programs and informed choice to societal paternalism:

- "pressure schools and other public facilities not to have vending machines...,"
- "encourage a food production policy based on small regional food producers...,"
- "recommend fiscal pricing policies for items that are high in free sugars and fats and are otherwise of questionable nutritional value..."
- "facilitate bike paths, exercise facilities in public paths, etc."

The epidemiological triad model unfortunately oversimplifies the etiologies of extremely complex, multi-factorial diseases and conditions like obesity, and in addition, ignores the undernourished, and the poverty that they live with on a daily basis. The so-called "host" most certainly is endowed with risk factors such as, genetic makeup and family history that must be taken into account and may not be subject to modification. The "vectors" related to obesity are not simply food and nutrients, but are also levels of physical activity and inactivity. In addition, there are multiple factors within this vector paradigm that are a function of the host's behavior.

The report's failure to address these results is an analytical bias that understates the role of the individual in managing his or her weight, while overstating the role government could or should play. To date, there is no evidence that individual behavior, such as dietary habits, food choices, and the desire to be physically active, can be manipulated by mandates of legislative bodies or regulatory impositions. Even if government mandates could alter behavior, the side effects of these mandates have not been considered nor have their effectiveness compared with simply allowing the individual freedom to choose, a fundamental tenet of the free market.

Third, urbanization and mechanization have created secular societal trends that foster greater propensity toward obesity that are not only diet-related. Without addressing this reality, analysis tends to overstate the role of diet and understates the role of other lifestyle choices that mitigate overweight and obesity. For example, urbanization and mechanization have produced new opportunities and challenges in developing countries that include fewer physically demanding jobs and more sedentary ones. Despite this secular trend, the draft report presents minimal discussion of ways to encourage more physical activity among those who are becoming increasingly less active. In general, that means more exercise for most people in countries whose workforce is engaged in decidedly sedentary jobs. The cultures in many developing countries view overweight and a sedentary lifestyle as a sign of status, wealth, and health. The concept of exercising for health is not established in the general community. This means that there must be comprehensive and collaborative educational efforts by all segments of society

to help people understand the need to balance energy intake and energy expenditure and make informed choices.

Fourth, many of the policy recommendations were not supported by the scientific review that noted equivocal or disparate results in the links between dietary components and obesity. For example, at several points the draft report cites evidence based on aggregate level data to support a claim on possible causes of obesity. Arguments based on these data must be interpreted with great caution because of the well-known statistical phenomenon called the ecological fallacy.

It has been known since at least 1950 that aggregate-level data cannot be generalized to explain individual-level behaviors.[1,2] It is very difficult, some say impossible, to draw conclusions about individual behavior based on aggregate level data. For example, one could construct a scenario in which the population as a whole is eating out at fast food restaurants and is becoming more obese, but the population estimates do not explain individual-level data. The basic problem is that the people who are eating out more often and the people who are gaining weight may not be the same people.[3] This applies to all of the aggregate level inferences in the draft report.

Fifth, the global policy recommendations in the draft report offer no evidence that envircnment-based interventions have any effect on obesity prevalence. The draft report cites that of 24 school-based interventions, only one showed an effect on obesity and that one study saw positive results in girls, but not boys. Also cited is a study published by Ludwig and his associates that tracked soft drink consumption among growing 11- and 12-year children. The authors showed that during the 18-month study period 37 children were newly categorized as "overweight," while 35 children became "normal" weight.

A large body of literature shows carbohydrates, in general, and added sugars in particular, are not associated with overweight and obesity.[4,5,6,7,8] This literature includes:

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[1] Robinson WS. 1950. "Ecological Correlation and the Behavior of Individuals." ***American Sociological Review*** 15: 351-357.

[2] King G. 1997. A ***solution to the ecological inference problem: reconstructing individual behavior from aggregate*** data. Princeton, N.J.: Princeton University Press.

[3] Forshee RA. Nutrition Research and the Ecological Inference Problem: Determining the Causes of Obesity and Poor Nutrition. North American Association for the Study of Obesity, Long Beach, CA, October 29-November 2,2000.

[4] Glinsmann WH, Irausquin H, Park YK. Report from FDA's Sugars Task Force: evaluation of health aspects of sugars contained in carbohydrate sweeteners. J Nutr 116(11S):S1-216, 1986.

[5] The Surgeon General's Report on Nutrition and Health. Public Health Service, U.S. Oepartment of Health and Human Services. Washington, DC: U.S. Government Printing Office, DHHS(PHS) Publication No. 88-50210, 1988.

[6] National Research Council. Diet and Health: Implications for Reducing Chronic Disease Risk. National Academy of Sciences. pp. 273-290, 1989.

[7] Clydesdale FM. Nutrition and health aspects of sugars. Am J Clin Nutr 62:161S-296S, 1995,

[8] Food and Agriculture Organization/World Health Organization. FAO/WHO Expert Consultation on Carbohydrates in Human Nutrition. Carbohydrates in Human Nutrition. pp.1-129, 1998.

1) FDA's Sugars Task Force: Evaluation Of Health Aspects Of Sugars Contained In Carbohydrate Sweeteners.

2) The Surgeon General's Report on Nutrition and Health. Public Health Service, U.S. Department of Heaith and Human Services.

3) National Research Council. Diet and Health: Implications for Reducing Chronic Disease Risk. National Academy of Sciences.

4) Clydesdale FM. Nutrition and health aspects of sugars.

5) Food and Agriculture Organization/World Health Organization. FAO/WHO Expert Consultation on Carbohydrates in Human Nutrition. Carbohydrates in Human Nutrition.

In addition, a recent study conducted by the center showed that, controlling for other factors, children and adolescents who consume more added sugars do not have higher BMI scores.[9] It should be noted that sugar-sweetened soft drinks and fruit juices are not cited in 4.1 "Strength of Evidence" of the preface, and the text for 'Sugar in drinks" in Annex 2 does not appear sufficiently strong to conclude that the evidence for promoting weight gain is "consistent and moderately strong." Yet, this is listed in Table 3 of the preface as having probable evidence for increasing risk for weight gain and obesity. Subsequent recommendations reflect this bias.

Sixth, the draft report avoids mention of more than 800 million victims of food insecurity. The fact is that the world population is growing rapidly, and will reach 8-10 billion people by 2050. Most of that growth is currently in developing countries that already have food insufficiency problems and many of the recommendations would hurt this subsistence population. The production of a safe and nutritionally adequate food supply for all must remain the priority. Healthier economies, better understanding of nutrition science, and improved applications of agricultural and food technologies will create a reliable food infrastructure and industry that produces a safe, wholesome, consistent food supply.

Certain aspects of the draft report oversimplify food production systems. With regard to food policy, there is no recognition of the improvements in health of populations as a result of hawesting, storing, preserving, and processing seasonal surpluses of commodities, which are transformed to basic, palatable, nutritious, and affordable foodstuffs by the food industry. This knowledge and contribution appears sadly lacking in the draft. Rather than denigrate the contribution of food production and distribution of foods to urban and rural populations, the report should acknowledge and praise the contributions of the agriculture and food industries in making adequate amounts of safe and good quality foods available, while doing this in a sustainable and environmentally friendly way. Criticisms of foods and food groups must be based on sound scientific

[9] Storey Mt, Forshee RA, Weaver AR, Sansalone WR. Demographic and Lifestyle Factors Associated with Body Mass Index Among Children and Adolescents. Ceres® Working Paper Number 1, 2002.

evidence and data that reflect the current consensus of informed experts. We therefore urge WHO to seek individuals who are experts in food production and distribution systems to provide that particular insight.

Finally, there are suggestions that taxes and subsidies should be instituted to discourage or encourage —as appropriate —the consumption of certain foods.[10] However laudable the objectives, actual experience with taxes and subsidies demonstrate that neither are efficient means of achieving the goal of changing food patterns. Taxes frequently have long-term, indirect, and unforeseen effects that are cumbersome and costly to implement. Moreover, there are perverse impacts that contradict the purposes for which they were intended, placing the heaviest burden on the world's subsistence population. For example, a tax on a food intentionally raises the price of that food compared with its alternatives. There is a presupposition that the consumer will be enticed to switch from the higher priced food and substitute the "desirable" food(s) that is comparatively cheaper. This also presupposes that the consumer will have the knowledge and desire to switch to the "desirable" food rather than some equally "undesirable" alternative. Thus, to be effective, the tax relies on the consumer being informed enough to select a "desirable" food and to know the reason why he/she should behave differently. If consumers are so informed and they choose to behave differently, they will switch without the tax.[11]

We urge WHO to consider that higher food prices imposed by a regressive tax will be paid by people who can least afford them, thus reducing their disposable incomes. If the switching between food choices is delayed or does not occur, consumers will pay more for food and the effect of the tax is to simply make them poorer. This is true where a high degree of "price inelasticity of demand" exists for the taxed food product. The end result is the government becomes the primary, and perhaps, the sole beneficiary of the tax revenues. These points should be carefully reviewed since the recommended actions place the greatest societal hope on the weakest scientific justification.

In summary, we urge WHO to:

1) withdraw the current version of this draft report because it fails to address the other key factor in preventing obesity-physical activity and fitness;

2) re-examine the policy recommendation that imposes food taxes that are likely to be ignored by the rich and middle-class, and further impoverish the poor; and

3) re-submit a revised report to a balanced, independent panel of referees, experts in nutrition, physical activity, economics, and food production,

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[10] Ortiz, et al. *2002; California Childhood Obesity Prevention Act.* S.B. 1520.
[11] Frank RH. *Microeconomics and Behavior,* fourth edition, McGraw Hill Publishing. 2000. pp. 55-59, 113-117, 122-131.

manufacturing, and distribution systems, who can provide the credible review needed for global acceptance, adoption, and implementation by member states.

Thank you for considering these comments.

Yours respectfully,

Maureen L. Storey, PhD
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Appendix 2

Comments submitted by the Center for Food and Nutrition Policy at Virginia Tech to the U.S. Food and Drug Administration, November 21, 2003.

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An *FAO Center of Excellence for Food and Nutrition Policy*

November 27, 2003

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

RE: Docket No. 2003N-0338: Obesity Issues
68 Fed. Reg. 03-25645 (October 8, 2003)

The Center for Food and Nutrition Policy ("Center" or CFNP) at Virginia Tech in Alexandria is an independent, non-profit research and education organization that is dedicated to advancing rational, science-based food and nutrition policy. It is recognized as a Center of Excellence on such matters by the Food and Agriculture Organization (FAO) of the United Nations. The Center uniquely operates like an independent "think-tank," while maintaining its academic affiliation with Virginia Tech, a major land-grant university. The research, education, outreach, and communication activities of the faculty are conducted in a relevant, time-sensitive manner that helps inform the public policy process on food and nutrition issues.

Encompassed in the Center's activities on nutrition policy are its interests in policy and regulatory issues involving dietary guidance, food labels, labeling, and obesity.

The Center recognizes and respects the difficult task that the Food and Drug Administration (FDA) faces in expending finite resources on the numerous and diverse issues that affect public health. As such, the Center respectfully submits the following comments in response to the FDA's request for comment on obesity issues, docket no. 2003N-0338 as published in the Federal Register.[1]

The comments contained herein address FDA's question #6: "Based on the scientific evidence available today, what are the most important things that FDA

[1] **Federal Register: Notices. October 8, 2003, Volume 68, Number 195, pages 58117-58118.**

could do that would make a significant difference in efforts to address the problem of overweight and obesity?"

Rigorous "Weight of the Evidence" Process for Obesity Initiatives Is Needed

On January 16, 2003, Food and Drug Administration Commissioner Mark McClellan announced the formation of an internal task force—Consumer Health Information for Better Nutrition—to develop scientific guidance for establishing standards in making qualified health claims on food and supplement labels.[2]

The charge to the task force was to:

- "Report on how the agency should apply the 'weight of the evidence' standard established under the consumer health information initiative for qualified health claims on conventional foods.
- Develop a framework of regulations that will give these principles the force and the effect of law.
- Identify procedures for implementing the initiative, as well as determining the organizational staffing needs necessary for the timely review of health claim petitions.
- Develop a consumer studies research agenda designed to best present scientifically based information to consumers in a truthful and non-misleading way, and to identify the kinds of information known to be misleading to consumers."

On July 10, 2003, FDA issued industry guidance and interim procedures for making qualified health claims on human foods and dietary supplements.[3] In like fashion, the Center for Food and Nutrition Policy urges FDA to establish a similar rigorous framework for evaluating the "weight of the evidence" in establishing regulations, guidance, educational campaigns, or research agendas that are within FDA's scope of responsibility in addressing the issue of overweight and obesity in the American population.

Few reasonable scientists disagree that excess body weight is the result of an imbalance between energy (calories) consumed and energy expended. But there are many factors—non-modifiable and modifiable—that contribute to one's risk of becoming overweight. Non-modifiable risk factors for overweight include genetics (that may include race/ethnicity), age, and gender. Modifiable risk factors include lifestyle habits, such as levels of physical activity at work and during leisure time, sedentary behaviors, and diet.

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[2] http://www.cfsan.fda.gov/~dms/nuttftoc.html
[3] http://www.cfsan.fda.gov/~dms/hclmgui3.html#intro

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Non-Modifiable Factors Are Strongest Determinants of Overweight

Genetics, Race and Ethnicity. Research shows that some people may have a genetic predisposition to becoming overweight, but this susceptibility may not be expressed phenotypically. Modifiable lifestyle factors are also important variables in whether a genetically predisposed individual becomes overweight.[4] The strength of genetics has been shown in elegant studies conducted by Bouchard and colleagues in identical twins.[5]

Race/ethnicity also appears to be a significant factor in becoming overweight; evidence suggests that race/ethnicity affects the timing and rate of weight gain. Williamson and his colleagues found that African-American women tended to gain more weight during perimenopause than did white women.[6] This is in contrast to the findings of Hamman and co-workers who noted no extra weight gain among Pima Indian women at the time of menopause.[7] However, this may be due to the fact that the Pimas tend to gain weight at a much earlier age.

Age and Gender. Advancing age appears to be related to increased body weight even among healthy, active men and women. Increased body weight, however, is related to changes in resting metabolic rate (RMR), which comprises about 60-75 percent of daily energy expenditure.[8,9] Poehlman and colleagues found that the age-related decline in RMR among healthy women was not an independent effect of age, but rather was strongly related to a decline in fat-free weight accounting for 72 percent of the variance in RMR. These investigators predicted that in healthy women, there would be a 0.6 percent decline per decade in RMR between ages 18-50 and a 4.0 percent decline per decade between 51-81 years of age. A re-analysis of a similar study conducted among men showed the same curvilinear relationship between RMR and age. The declines in RMR among men occurred at a younger age (41 years) than women, and at nearly double the rate of decline seen in women.[6,10]

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[4] Leibel RL, Chung WK, Streamson CC Jr. The molecular genetics of rodent single gene obesities. J Biol Chem 1997; 272: 31937-31940.

[5] Bouchard C, Tremblay A. Genetic influences on the responses of body fat and fat distribution to positive and negative energy balances in human identical twins. J Nutr 1997; 127: 943S-947S.

[6] Williamson DF, Kahn HS, Remington PL, Anda RF. The 10-year incidence of overweight and major weight gain in U.S. adults. Arch Intern Med 1990; 150: 665-672.

[7] Hamman RF, Bennett PH, Miller M. The effect of menopause on serum cholesterol in American (Pima) Indian women. Am J Epidemiol 1975; 102: 164-169.

[8] Poehlman ET, McAuliffe TL, Van Houten DR, Danforth Jr. E. Influence of age and endurance training on metabolic rate and hormones in healthy men. Am J Physiol 1990; 259 (Endocrinol Metab 22): E66-E72.

[9] Heymsfield SB, Gallagher D, Poehlman ET, Wolper C, Nonas K, Nelson D., Wang ZM. Menopausal changes in body composition and energy expenditure. Experim Gerontol 1994; 29: 377-389.

[10] Poehlman ET, Goran MI, Gardner AW, Ades PA, Arciero PJ, Katzman-Rooks SM, Montgomery SM, Toth MJ, Sutherland PT. Determinants of decline in resting metabolic rate in aging females. Am J Physiol (Endocrinol Metab 27) 1993; 264: E450-E455.

Loss of fat-free weight significantly influenced RMR among men and women, but men experienced the decline in fat-free weight at an earlier age than did women. Men began to lose fat-free weight around age 35 years, whereas women experienced this loss around 48 years of age. The rate of decline in fat-free weight was similar between men and women, however. These studies and others suggest that strategies to increase physical activity may mitigate losses of fat-free mass leading to the age-related decline in RMR.[11,12] Thus, Williams recommended that guidelines targeting older adults should urge substantially greater levels of physical activity, or develop weight standards that are adjusted for older age groups if physical activity does not increase over time.

Non-modifiable risk factors appear to be the strongest determinants of overweight among children and adolescents as well as adults. The Centers for Disease Control and Prevention (CDC) have developed gender-specific "growth" charts for children showing increases in body mass index (BMI) with age.[13] A study conducted by Forshee and his colleagues showed that gender, age, race/ethnicity were better predictors of overweight than lifestyle habits of 6-11 year old children and 12-19 year old adolescents. These investigators also noted that among lifestyle habits, sedentary behavior—as measured by hours of television/video watched—predicted body mass index more strongly than did dietary components.[14] The relationship of physical activity, or the lack of it, with overweight among children and adolescents is consistent with the studies among adults that are cited here.

As noted in the previous section, physical activity is an important lifestyle component that may help prevent, or at least slow, unhealthy weight gain among children, adolescents, and adults. The CDC, a "sister" agency of FDA, developed the Youth Media Campaign (YMC) to encourage greater physical activity among 9-13 year old school children.[15] The CDC conducted a longitudinal survey of this age group and the children's parents. The report found that among the group of 9-13 year olds surveyed, 61.5 percent did not participate in any organized physical activity, and 22.6 percent did not participate in *any* physical activity during their non-school hours. Striking disparities in organized physical activity were observed among non-Hispanic black and Hispanic children compared with non-Hispanic white children. Nearly 47 percent of white children

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[11] **Van Pelt RE, Jones PP, Davy KP, DeSouza CA, Tanaka H, Davy BM, Seals DR. Regular exercise and the age-related decline in resting metabolic rate in women. J Clin Endocrinol Metab** 1997; 82: 3208-3212.

[12] **Williams PT. Evidence for the incompatibility of age-neutral overweight and age-neutral physical standards from runners. Am J Clin Nutr** 1997; **65:** 1391-1396.

[13] **Centers for Disease Control and Prevention, National Center for Health Statistics, www.cdc.gov/growthcharts/**

[14] **Forshee RA, Storey** ML, **Weaver AR, Sansalone WR. Demographic and lifestyle factors associated with body mass index among children and adolescents. Intl J Food Sci Nutr** 2003; **54:** 491-503.

[15] **Centers for Disease Control and Prevention. Physical activity levels among children aged** 9-13 **years—United States,** 2002. **MMWR** 2003; 52: 785-788.

reported participating in organized physical activity during the preceding seven days, but only 24 and 26 percent of black and Hispanic children, respectively, reported similar activity. There was much less difference in reported free-time physical activity, however. For example, 79 percent of white children reported participating in free-time physical activity, while 75 percent of black and Hispanic children reported participation.

This suggests that physical activity is a must for all consumer communications if FDA and other federal agencies responsible for public health are to succeed in stemming rising obesity.

Few Changes Are Needed to the Nutrition Facts Panel to Combat Obesity
Some groups have suggested that FDA require additional labeling to combat the problem of overweight and obesity. As previously stated above, energy expenditure must be balanced with energy (calorie) intake to maintain a healthy weight. In so doing, consumers must have the information to properly assess caloric intake from foods consumed. In 1978, less than half of foods provided nutrient information on the package. But as more research suggested an important link between diet and health, there was greater demand for nutrition information on food packages. The Nutrition Labeling and Education Act of 1990 (NLEA; Public Law 101-535) mandated that nearly all FDA-regulated food packages display nutrient content—including calorie content—per serving of food. Regulations implementing NLEA took effect on May 8, 1994. Three years after implementation, research conducted by FDA showed that 96.5 percent of foods displayed a Nutrition Facts label and caloric content? One objective of NLEA—nutrition labeling—was therefore achieved. Hence, consumers can access the necessary information to calculate how many calories they are consuming in a serving of food.

Information, however, does not necessarily mean that consumers will have the education to make healthy decisions or that they will choose do so. Another objective of NLEA was to help consumers improve dietary habits through education, yet this objective has not been achieved in the 13 years since the law was enacted, or in the decade since the regulations were implemented. One of the key assumptions behind the NLEA was that policymakers presumed that consumers placed significant importance on nutrition when deciding which foods to purchase, and that reading the nutrition label would induce food choices that would lead to a healthier diet.

It should be recognized that some consumers do use the nutrition label. Consumers who use the Nutrition Facts panel tend to be 1) white, 2) female, 3)

[16] **Brecher SJ, Bender MM, Wilkening VL, McCabe NM, Anderson EM. Status of nutrition labeling, health claims, and nutrient content claims for processed foods: 1997 Food Label and Package Survey. J Am Dietetic Assoc 2000; 100: 1057-1062.**

older, 4) more affluent, 5) already eating healthfully, and/or 6) have an important health concern.[17,18,19]

Analysis of the FDA's Food Label Use and Nutrition Education Survey (FLUNES) showed that the Nutrition Facts panel was used most often to assess the level of a certain characteristic of the food product and to avoid a specific ingredient.[20] This analysis suggested that the nutrition label was not used in making first-time purchases, comparing brands, preparing meals, or deciding how much of the product to eat. Surprisingly, in this survey consumers did not use the Nutrition Facts panel to determine the nutritional content of the food, or to confirm the truth of an advertising or packaging claim.

Even people with serious health problems do not fully utilize information on food labels. For example, a study conducted in four family medicine clinics in southwest Missouri showed that patients with high blood pressure were 63 percent more likely to look for sodium content on the food label than patients with normal or low blood pressure; and patients with high blood cholesterol were more likely to look for saturated fat content. Neither of these groups of patients, however, was more likely than others to look for additional nutrition information on the label.

Adolescents also appear to limit their use of the nutrition label. For example, a study conducted among 90 high-school aged adolescents showed that they are more likely to attend to information presented on the principal display panel (the front) of food packages than they are to information in the Nutrition Facts panel.[21] The top three reasons these adolescents gave for choosing certain foods were preference/taste, custom/habit, and price/cost. The front label/nutrition claim, nutrient label, and television advertising ranked fifth, twelfth, and thirteenth, respectively, among their reasons for selecting certain food items.

This strongly suggests that other factors determine consumers' food choices regardless of the availability of nutrition information that is easily accessed on the food label. The Center therefore finds little rationale for making major changes to the nutrition label to address the problem of overweight and obesity.

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[17] **Kreuter MW, Brennan LK, Scharff DP, Lukwago SN.** Do **nutrition label readers eat healthier diets? Behavioral correlates** of **adults' use** of **food labels. Am J Prev Med** 1997; 13: 277-283.
[18] **Neuhouser ML, Kristal AR, Patterson RE. Use** of **food nutrition labels is associated with lower fat intake. J Am Diet Assoc** 1999; 99: **45-53.**
[19] **Papakonstantinou E, Hargrove JL, Huang** CL, **Crawley CC, Canolty NI. Assessment** of **perceptions** of **nutrition knowledge and disease using a group interactive system: the Perception Analyzer**. J **Am Diet Assoc 2002;** 102: 1663-1668.
[20] **Brooks KC. The nutrition facts panel: who uses it and** how **is it used? Practicum for the Master of Public Policy degree, Georgetown University, May** 2000.
[21] **McCullum C, Achterberg CL. Food shopping and label use behavior among high school-aged adolescents. Adolescence** 1997; **32:** 181-197.

Summary of Comments

In summary, the Center urges FDA to:

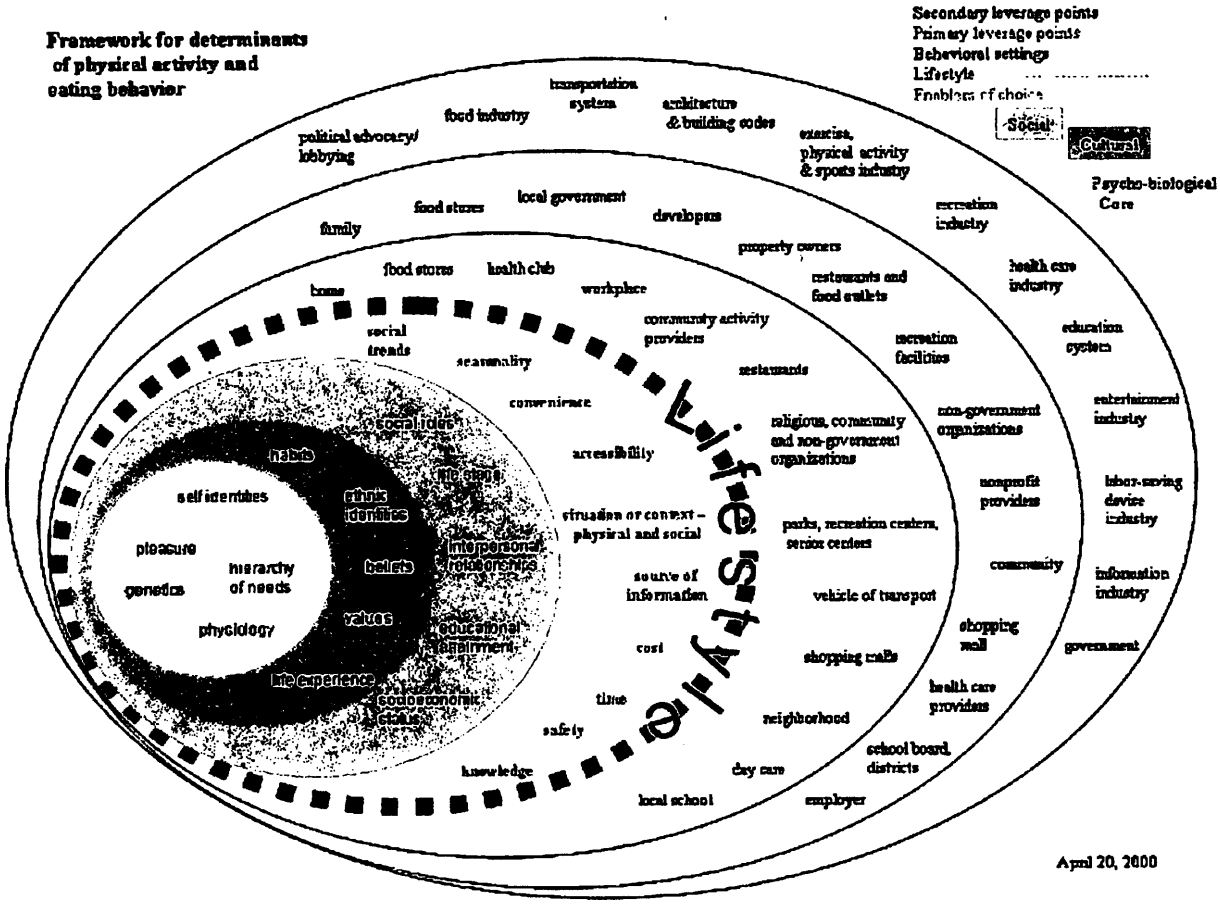
1. use an evidence-based evaluation of the currently available science to determine the most important factors in the development of overweight and obesity;
2. establish regulations or amend regulations based on the strength of the evidence and that are within the scope of FDA's mission and responsibility;
3. begin an education campaign in collaboration with the food industry to help consumers understand the nutrition label; and
4. collaborate with the Department of Education to institute age-appropriate nutrition education curricula in elementary, middle, and high schools.

Respectfully submitted,

Maureen L. Storey, PhD
Director and Research Associate Professor

Appendix 3

Framework for Integrating the Individual with the Environment, Partnership for the Promotion of Healthy Eating and Active Living."



[10] The Partnership to Promote Healthy Eating and Active Living, www.ppheal.org/summit. Accessed January 10,2004,