STATEMENT OF THE AMERICAN OBESITY ASSOCIATION BEFORE THE FOOD AND DRUG ADMINISTRATION PUBLIC MEETING ON OBESITY
MORGAN DOWNEY, EXECUTIVE DIRECTOR
WASHINGTON, D.C. October 23, 2003
Re: Docket # 2003N-0338

The American Obesity Association (AOA) is pleased to have this opportunity to address the urgent national and international problem of obesity and the role of the Food and Drug Administration (FDA). We applaud Secretary Tommy Thompson's leadership on the issue of obesity and the significant interest expressed by the leadership of HHS in this issue.

AOA is a non-profit tax-exempt educational and advocacy organization. We have some seven hundred members, both professional and lay. Our financial support comes principally from pharmaceutical research and development companies as well as other companies in the weight management field.

Obesity is the most prevalent, fatal, chronic disease of the 21st Century. The World Health Organization (WHO) has identified obesity as one of the ten leading health risks in the world today; one of the top five in the developed world. WHO reports that over one billion people are overweight in the world out of a population of 6 billion and that 300 million persons (5%) are clinically obese. WHO projects 3 million deaths annually worldwide from obesity rising to 5 million by 2020.

In the United States, 65% of adult Americans are overweight and 31% are clinically obese. Fourteen percent of American children and adolescents are obese. Obesity is unique in that it is a chronic disease that is increasing at rates previously only seen with infectious diseases.

Obesity is a leading cause of mortality, morbidity, disability, and discrimination in health care, education, and employment. According to a recent RAND study, the health consequences of obesity are as significant or greater than smoking, problem alcohol consumption and poverty. The consequences of obesity include various cancers, heart disease, stroke, type 2 diabetes, osteoarthritis, sleep apnea, and problem pregnancies and childbirth among others.

Too often, discussions about obesity seem to focus on normal weight persons at risk for becoming obese or persons with just borderline obesity. It should be kept in mind that persons would have morbid or severe obesity, defined as a Body Mass Index or BMI of 40 or greater, approximately 100 pounds overweight, includes some 10 million Americans. For comparison purposes, the population with Alzheimer's disease is about 4 million. This population is the one where the

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adverse health and socioeconomic effects of obesity are most pronounced and which suffers the greatest lack of access to health care and treatment.

Obesity is poorly treated in the medical community even though effective treatments are available including bariatric surgery, FDA approved medications, physician counseling, dietitian services and behavioral interventions. Coverage for these treatments is modest to poor in both governmental and non-governmental health insurance programs. Inexplicably, the very insurance programs that do not reimburse for weight maintenance do cover the costs of treating the diseases caused by obesity. The desire for effective methods of weight management can lead to adverse interventions by consumers including the initiation or continuation of tobacco smoking and the use of ineffective or harmful consumer products.

At the outset, we believe the HHS must rethink its traditional approaches to obesity and adopt a paradigm which is more scientifically driven than current approaches. This paradigm involves the following understandings:

A. Obesity is not a behavior; obesity is excess adipose tissue.
B. Obesity is a disease because it meets any rational definition of "disease".
C. Obesity is a fatal, chronic, relapsing disease that is at least as complicated to treat as heart disease or cancer.
D. Obesity is a problem that will largely be solved by more research.
E. Obesity prevention and treatment includes more than just diet and exercise, as the effectiveness of these treatments over the long term has been poor.
F. Obesity is a global problem arising from a combination of genetic, environmental and behavioral factors.
G. We do not know now how to prevent and effectively treat obesity over the long-term, with the exception of bariatric surgery for persons with morbid obesity.
H. If we do not drastically and quickly expand the research base of obesity and develop new treatments, the entire health care system in the United States is at risk.
I. Simplistic assertions that obesity is easily prevented or easily remedied do a disservice to persons with obesity and inhibit discovery of effective solutions.

Presenters have been asked to address six questions which we will. However, We would like to point out that these questions are too limiting and restrictive to fully address obesity in the United States.

Our comments address four issues which are primarily within the jurisdiction of the FDA. The FDA can play an invaluable role in other recommendations which are primarily under the jurisdiction of other components of the Department of Health and Human Resources.

The four specific recommendations for the FDA cover food labeling, guidances for developers of pharmaceutical products for the treatment of obesity, approval of other drugs and devices and enforcement.

Food Labeling

Even the most motivated person, seeking to manage their weight will be confused by the information on food labels, the Food Pyramid and the Dietary Guidelines. The Nutritional Label has become as complicated as the package insert on FDA approved drugs. Greater and greater levels of information may be useful to some but they are of little value if too complicated for consumers to understand. The FDA should require a large label on the front of each package of food giving the package's total calories. Consumers seeking to control their weight will have clear information and can make allocations according to their own usage or portions. This would stop the gaming of calorie information by food companies who are now allowed to report their own calorie per portion information. Restaurant chains should also be required to post calories on their menus.

Obesity Drug Development

AOA was very pleased to see the Commissioner of the Food and Drug Administration announce earlier this year a commitment to revise its guidances for approval of new drugs for the treatment of obesity. For persons desiring to treat their overweight or obesity, pharmaceuticals, in conjunction with diet and exercise, offer the greatest likelihood for significant new developments.

In April 2003, AOA convened a meeting of some dozen pharmaceutical and biotech companies to discuss problems with the current FDA guidances at which Dr. Lester Crawford provided valuable insights. The consensus of the meeting was that not only are the current guidances out of date scientifically, they are inconsistent with guidances in other areas, such as type 2 diabetes, hypertension and hypercholestolemia, Also, there was consensus that in the past he attitude of the FDA has been to impose significant roadblocks to R&D companies invested in finding new therapies for obesity.

AOA recently held a second meeting of interested companies. We will be prepared in the very near future to present to the FDA specific suggestions for improving the guidances for obesity pharmaceutical products. We look forward to an exchange of views with the FDA and other stakeholders to move quickly on revising the guidelines.

Approval of Drugs and Devices

The FDA is aware that there is a growing concern about drugs which act to unintentionally increase weight in users. This area needs greater research and new drugs should be adequately evaluated for weight increasing effects.

In addition, when FDA reviews medical devices, it should assure that the devices have been tested in obese populations and can physically be accessed by persons with obesity, especially morbid or severe obesity.

Enforcement

The continuing presence and aggressive advertising of weight control dietary supplements and other products is a major health care problem. We urge the FDA to allocate more resources to such enforcement and to expand collaborations with other law enforcement agencies, such as the Federal Trade Commission and state and local prosecutors.

Regarding the specific questions put forth from the Department.

1. **What is the available evidence on the effectiveness of various educational campaigns to reduce obesity?**

We are aware of studies which have shown a beneficial impact on body weight of reduced television viewing but others which have tried to improve diet or physical activity have either been very small or have not shown positive long-term body weight reduction.

For an issue as much in the public eye as obesity, the lack of education is appalling.

Due to television coverage, many in the public assume that when we talk about obesity they believe that we are talking about morbid obesity. On television, the public often sees persons who are 100 pounds overweight described as obese; rarely do they see persons at the defined level of obesity, about 30 pounds overweight. This means that many do not feel they or family members/co-workers are at risk. When the NIH Guidelines for the Treatment of Obesity were issued, there was widespread public confusion over the definition of overweight. To many, it seemed an arbitrary cutoff, rather than a recognition of the level at which weight-related health problems develop. HHS and NIH failed to respond to this misperception in the public and media. Because of this misperception, the public less likely to take health warnings seriously. HHS could ameliorate this by providing visual aids to television and other media outlets on what obesity truly looks like in a compassionate manner and by encouraging government and private partnerships to provide opportunities for industry to disseminate these messages.

The level of physician and other health professional knowledge of obesity and its treatment is tragically low. HHS should use its health education resources to encourage education in medical schools and other health professional schools about obesity and its treatment. We propose that the HHS set aside funds to develop faculty programs for obesity education and research in medical schools, similar to the programs for primary care medicine and women's health that have insured that specialists in these areas are in most of the medical schools in the country.

Schools have abdicated their responsibility to provide students at all levels with skills to understand their body weight and caloric requirements. In addition, schools have drastically curtailed physical activity for their students while providing greater access to vending machines and bringing in fast food franchisees to provide food services. DHHS should initiate an aggressive program with the Department of Education to amend federal and state education laws to require the provision of age-appropriate obesity, nutritional information and portion size information

Several surveys, including one conducted by AOA, indicate that parents have little understanding of the importance of their children's weight as well as family strategies to manage weight effectively. AOA recommends that HHS and the Department of Education undertake a campaign focused on parents of elementary school children, in particular, to allow them to assess their child's weight status and appropriate strategies for weight management.

2. **What are top priorities for nutrition research to reduce obesity in children?**

This question assumes that obesity in children is a nutritional question. It does not address questions such as the weight and height of parents, breastfeeding practices and television viewing which have been studied for their effect on childhood obesity. Reducing obesity in children, as in their parents, may involve multiple factors in addition to nutrition research.

Body fat is now known to be regulated by several hormones and neuropeptides, including leptin and ghrelin. Food products such as glucose, amino acids and fatty acids affect the production of the hormones insulin, growth hormone, insulin-like growth factor and leptin act on specific receptors in the hypothalamus and other areas of the brain to regulate feeding behavior and energy metabolism. The next stages of the human genome program hold the promise to integrate the molecular understanding of normal body weight regulation with abnormal body weight regulation. Fresh insights on the significant racial and ethnic disparities in obesity and its comorbid conditions are foreseen. With such information, more precise and informed prevention strategies, behavioral interventions, pharmacology, and surgical interventions can be developed and tested. Such prevention and treatment strategies will give rise to questions of economic efficiency and legislative and regulatory approaches. The current lack of attention in medical training and health professional disciplines on obesity can be directly and immediately approached through programs to develop obesity researchers and health education campaigns. Research needs to also be greatly expanded on a global scale. Obesity is rising in virtually every country of the world except for sub-Sahara Africa. There are significant differences in these cultures and their differing rates provide a natural laboratory to understand the interaction of various causal factors.

Unfortunately, it must be recognized that the commitment of the National Institutes of Health to the obesity epidemic has been wholly inadequate. Billions of dollars are spent on the conditions caused by obesity; pennies on obesity itself. Broad areas of obesity research are under-supported. In addition, obesity is situated at the lowest rung of the NIH hierarchy, guaranteeing that new initiatives are not developed and that there is no articulate, scientifically based voice on obesity. In summary, despite obesity impact on health, despite its increasing over the last twenty years and despite the doubling of the NIH budget over the last 5 years, obesity remains in the budgetary and organizational cellar of NIH.

Therefore, we propose at a new National Institute of Obesity be established at the National Institutes of Health. We see it has having seven components or divisions:

1. Basic research on adipose tissue
2. Epidemiology and Population Studies.
3. Genetics, Metabolism and Disease Development;
4. Neuroscience and Behavioral Research;
5. Prevention, Therapeutic Development and Clinical Trials,
6. Economics and Health Policy, and,
7. Training and Education.

3. **What is the available evidence supporting whether public efforts should prioritize behavioral interventions to prevent obesity versus medical interventions to treat obesity?**

We think that the formulation of the question is part of the problem. The question itself is divisive and not scientific. Why are behavioral interventions competing against medical interventions rather than behavioral and medical interventions combined? Current scientific thinking envisions treating obesity through a variety of interventions over a lifetime. These approaches are highly likely to be used in multiple, combined forms, not in single "either-or" modalities. AOA Research Foundation recently completed a comprehensive review of the literature on combination therapies and found very little research in this area. The HHS should recognize that the future fight against obesity will entail a multiplicity of therapies. HHS would not ask whether to prioritize behavioral or medical interventions for other public health problems, such as HIV/AIDs. We do not say we only want to prevent SARS, not treat patients with it. Both interventions have important and complimentary roles in addressing obesity.

<u>Prevention</u>

Prevention of obesity and the complications of obesity are of critical importance. However, there is an amazing paucity of reliable information on how to prevent obesity. In addition, the important community-based programs now arising around the country are being carried out without independent reliable

evaluations. Thus, after those programs have been implemented we will not know what really works and what does not.

HHS needs to be realistic about prevention. The federal government encourages massive over-production of food. The federal government expends approximately $72 billion dollars a year on agricultural subsidies. This massive investment results in production of nearly twice the calories the U.S. population requires. This over production reduces the cost of foods to consumers, encourages portion sizes to increase without regard to the cost of the food and encourages massive marketing campaigns as companies strive for market share. In addition, the US Department of Agriculture and many states have programs to increase consumption of particular foods such as dairy, meat and corn produced in those states. The relevance of these programs to our Nation's health must be rethought. Through the Federal Communications Commission, the government is encouraging children viewing of television and increased television utilization by forcing communities to adopt high definition television systems (HDTV). Food companies are able to heavily advertise to children and consumers through the deductibility of advertising expenses on their corporate income taxes. Our commercial and industrial policies encourage information technology and the service economy which are much less labor intensive than our earlier industrial and agricultural basis. Our transportation policies encourage use of the private automobile and discourage means of transportation which would expend more calories.

HHS needs to be a voice to Congress and other federal agencies on the implication of these policies. None of these policies were created with the intention of creating obesity. However, we can no longer afford to ignore the putative impact of these policies on creating the energy consumption and expenditure experience of our people.

In addition, we recommend consideration of a novel proposal we would like to offer. According to USDA, advertising of food is a $7 billion dollar annual investment. Again, according to the USDA, most of this advertising investment is expended on foods at the top of the Food Pyramid, i.e. the most calorically dense foods of low nutritional value. We propose that HHS and the Department of the Treasury examine a change in the corporate tax laws. Currently all such advertising expenditures are deductible. Our proposal would require food companies to segment these expenditures into three categories: Category A would include foods of high nutritional value. Category B would comprise foods of modest or neutral nutritional value and Category C would include foods of low or minimal nutritional value. Criteria for each category would be established using USDA established protocols. Each food company would then allocate their advertising expenditures by category. Category C advertising expenditures would not be eligible for the deduction from corporate income. Category B advertising expenditures would be eligible for a one-to-one deduction. Category A advertising expenditures would, however, be eligible for a two- or three-to-one deduction. The Treasury Department would establish a modifier such that this formulation would be revenue-neutral, in other words, the federal government would not receive greater or lesser tax revenues as a result.

We believe the results of this proposal are four. First, companies could develop and fully market and advertise any product they wish. Second, taxpayers would only subsidize healthy foods not high calorie foods with little other nutritional value. Third, consumers would not be restricted in their choices in the least. Fourth, this proposal creates an incentive to shift the considerable marketing skill of food companies to healthier foods.

Too often, HHS only speaks about prevention and avoids any reference to treatment. This is unique in public health programs. We cannot imagine that HHS would only talk about preventing HIV/AIDs for example, and not address treatment. The messages from HHS need to be more balanced and not simply rely on nostrums about diet and exercise, as important as they are, to the detriment of other weight loss/management strategies as indicated by NIH in their Guidelines for the Treatment of Obesity.

Prevention may also be accomplished by encouraging communities to think about and plan the physical environments to be more conducive to physical activity. The federal government makes a great investment in roads, highways, airports, mass transportation and urban planning. We propose that the Department of HHS work with the Department of Transportation and other federal agencies on a Physical Activity Impact Statement, modeled after the Environmental Impact Statement. For each federally supported program, analysis would be made whether the proposed project (like a highway without sidewalks) is likely to increase or decrease the net physical activity of the community it serves. If it were foreseen that the project is likely to result in a decrease in physical activity, remedial steps would be necessary to take the project to at least a neutral intervention in the human environment.

Treatment

HHS has set a very poor model for managed care and the insurance industry in the treatment of obesity. The Medicare Coverage Issue Manual declares that obesity is not an illness and that no program payment can be made. The Medicare drug benefit legislation now before Congress excludes drugs for the treatment of obesity. The Medicare medical nutrition counseling benefit does not cover services for persons with obesity, with or without comorbid conditions. The Medicaid program also largely excludes drugs and surgery for the treatment of obesity, as well as behavioral counseling, nutrition education and physician supervised weight loss programs. The Indian Health Service excludes surgery for the treatment of obesity

HHS policies have created and supported discrimination against persons with obesity by these policies. AOA calls on HHS to

a. incorporate the NIH Guidelines for the Treatment of Obesity in its own programs such as Medicare, Medicaid and the Indian Health Service;
b. change the Medicare program's policy to recognize obesity as a disease;
c. encourage health maintenance organizations and traditional insurers to cover obesity treatments recommended by the NIH;

d. advocate that Congress include drugs to treat obesity in the pending Medicare drug benefit legislation and
e. advocate that Congress repeal the provision discouraging states to include drugs to treat obesity in the Medicaid program.

Both Medicare and Medicaid programs should commence demonstration projects to evaluate the effectiveness of various interventions in the elderly and Medicaid populations. These would include evaluations of surgery, drugs, lifestyle modification programs, and, nutrition counseling in individual and group settings.

The Centers for Medicare and Medicaid Services (CMS) needs to appreciate that the elderly obese Medicare population is increasing dramatically. In fact, the elderly-obese Medicare population is the fastest growing segment of the obese population. Obesity related comorbidities account for fully five of the top ten reported health conditions of Medicare beneficiaries. The impact of obesity on the Medicare population will increase in the foreseeable future as both baby-boomers reach Medicare eligibility and the population of disabled persons with obesity increases. CMS should be encouraged to work with National Institutes of Health to address this growing problem.

HHS should also launch a collaboration with the Department of Veteran's Affairs to promote treatment of this Nation's veterans with obesity, with the Office of Personnel Management concerning federal employees and with the Department of Defense concerning the problem of obesity in the military and among military families.

4. **What changes to food labeling could result in the development of healthier, lower calorie food and the selection of healthier, lower calorie foods by consumers? What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?**

We have addressed this issue above but we note that packaged food and restaurant menus should contain total calories.

5. **Based on the scientific foundation available today, what is the one thing HHS could do that would make a significant difference in the efforts to address the problem of obesity?**

The one thing HHS could do is not ask what is the "one thing" it could do. Changing the ever-increasing rates of obesity will take a massive and costly effort. Rather than looking for the least that HHS can do, the Department would be well advised to look at the most comprehensive program it can take to the crisis. We note that since 9/11/01, 3,023 Americans have died from terrorism. One report attributed to Vice President Dick Cheney the quote, 'Is there anything we have not done to protect Americans'? In contrast, since 9/11/01, some 600,000 Americans have died prematurely because of obesity. And we ask, "What is the one thing thing HHS can do"? It might be that every HHS program

develop the same sense of urgency which Dr. Julie Gerberding, the director of CDC, expressed when she said, "The biggest problem we face in America is not terrorism. The biggest health problem we're facing is obesity."

Several major areas are left untouched by the listed questions. They include Whether HHS is organized to deal with the obesity epidemic, the threat of increasing health insurance premiums on persons with obesity, stigma, discrimination and consumer protection.

A key question to be asked is, "Is HHS organized to address the national and international crisis in obesity?" The answer is no. No office is charged with monitoring the obesity epidemic, monitoring federal government's response and advising federal agencies and Congress on issues affecting obesity. We recommend that the Secretary establish in the Secretary's office an Office of Obesity Research, Prevention and Treatment and an advisory council. This office would be charged with coordinating HHS activities in relation to obesity and to work with other federal agencies and departments on issues affecting obesity. The Office should be charged with providing annual reports to Congress and the public on the progress in dealing with the obesity epidemic.

AOA was concerned with statements following the July 30, 2003 meeting to the effect that the Department was looking for ways to assist health insurance companies raise the premiums paid by persons with obesity. We object very strongly to the view that lean persons are subsidizing persons with obesity. This is a terrible approach for several reasons.

First, it constitutes a tax on the state of being obese. It assumes that obesity is a choice and is easily fixed. Neither assumption is true.
Second, not every obese person will require additional health care expenditures.
Third, this approach taxes some people for their health status but does not tax others. Should we tax women because they have higher health insurance costs? Should we tax African-Americans because they have poorer health than whites?
Fourth, why should we protect genetic information from insurance companies but allow them to impose greater costs merely because the health status is more apparent?
Fifth, persons with obesity actually subsidize lean persons because insurance covers their health needs but almost universally exclude coverage of treatments for obesity. Why should obese persons pay insurance premiums to treat your skin disease when your premium prohibits coverage of my obesity?
Sixth,, no health problem was ever solved by penalizing the patient. This one won't be either.
Seventh, this idea merely imposes greater stigmatization and discrimination on a significant component of the American public.
Eighth, it merely provides additional money for insurance companies while providing no countervailing benefit.
Ninth, this approach would fall disproportionally on women, African-Americans and Hispanic Americans.
Tenth, this proposal would likely increase still rising number of uninsured Americans as employers dismissed them from their employment.

Eleventh, dependents of obese-insureds who could not afford the extra costs would lose their health insurance coverage.

Persons with severe or morbid obesity have life-threatening problems in accessing routine health care not to mention treatment for their obesity. There are no social services or care coordinators who assist them with finding appropriate care, such as ambulances, social work services, or accessible technology. HHS should develop programs to train case workers, hospital discharge planners and other social support programs in assisting persons with obesity, especially morbid obesity.

In the United States, it is generally considered acceptable to discriminate against persons with obesity in education, employment and in health care. This discrimination, like all discrimination, causes enormous personal pain and the loss of valuable resources to the rest of society. Given that the morbidly obese population is at least 10 million, the prevalence of discrimination may equal that experienced by women, minorities and religious adherents. We urge HHS to undertake a systematic investigation of discrimination experienced by persons with obesity and subsequently to recommend to Congress remedial legislation to offset such discrimination.

There are numerous products marketed for weight loss with little or scant credible scientific evidence. Many products may be dangerous to consumers. We encourage the FDA and the Federal Trade Commission to strengthen its protection for consumers from all dangerous weight loss products.

Respectfully submitted,

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