

Written Statement of Stuart Trager, MD
Atkins Nutritionals, Inc.
to the
House Government Reform Committee
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Chairman Davis, members of the Committee, I am Dr. Stuart Trager, Medical Director of Atkins Nutritionals, Inc., the company founded by Dr. Robert Atkins to provide adherents of the Atkins low carbohydrate lifestyle with educational materials and products to help them achieve success on this nutritional strategy. I thank you for asking me to appear before your Committee. I commend you for tackling the serious national crisis in obesity by looking into ways the government can improve its recommendations to Americans on their diets.

Magnitude of Current Problem

With over 400,000 deaths annually in the United States attributed to obesity, the current epidemic has reached a state of true emergency, referred to as one of the top threats to the health of our nation by the Centers for Disease Control (CDC). This crisis has steadily increased over the past 30 years, with current estimates suggesting that 64.5% of American adults are overweight or obese and that approximately 1/3 of the population is in the category of clinical obesity, defined as a body mass index of more than 30 Kg/M². This alone represents a two-fold rise since 1980.

These statistics, combined with reports suggesting that our adolescents and teens are currently becoming increasingly sedentary -- one study showing that by the age of 18 or 19, up to 56 percent of surveyed girls reported no regular physical activity -- raise additional cause for concern. In our adolescent population, the prevalence of overweight and obesity has nearly tripled in the past 20 years, as compared to the doubling in the adult population. Even in a study looking at individuals trying to lose weight or not gain weight, fewer than 20% of these people are following recommendations to increase physical activity and reduce calories.

In addition to the tremendous human cost associated with lost lives due to obesity, we are gaining increased awareness of the relationship between this condition and numerous other significant diseases, including diabetes, coronary artery disease, hypertension, asthma, gout, gall bladder disease, stroke and certain cancers, including prostate, liver, kidney, colon and breast. Estimates of the number of years of life lost as a result of overweight and obesity range as high as 20.

With regard to quality of life, the effects are even more dramatic, resulting in the equivalent of aging 30 years. With current estimates placing a number of

individuals considered overweight or obese at more than 120 million, we are speaking of a problem of great magnitude.

Including direct and indirect costs, obesity has become a major contributor to the rising financial burden of caring for our population, with current estimates ranging up to \$117 billion. We are on pace to exceed the price of tobacco-related medical care in the next few years. This is also approximately 50% of the cost of treating all cancers (direct and indirect).

In 1995 alone, 5.7% of the US health expenditure was for individuals with body mass index over 29. From 1996 to 1998, overweight resulted in a 15% increase in annual per capita Medicare spending, with a 37% increase being associated with obesity. The direct costs of coronary heart disease, non-insulin dependent diabetes mellitus and hypertension attributed to obesity were estimated at \$42.62 billion.

Within the workplace, estimates suggest that \$20-30 billion per year are lost in productivity to lost time due to the increased medical problems linked to obesity. Employees lost 39.3 million workdays in 1994 due to obesity-related medical conditions, representing a 50% increase since 1988.

Urgency of Current Problem

At the same time we are fighting to manage the rising costs of healthcare, and to improve the quality of life for our population, we have seen little progress in combating obesity through the national dietary guidelines initially presented nearly 30 years ago. Despite relentless admonishment regarding the evils of fat consumption, we have seen only limited success in lowering the percentage of total fat intake, with overall fat consumption and total caloric intake actually increasing.

It is important to note that during this period of increased attention to fat reduction, carbohydrate intake has risen sharply. This increase occurs at a time when scientific studies are showing a clear relationship between carbohydrates and serum triglyceride levels. Elevated triglycerides and its concomitant suppressed HDL represent an independent risk factor for coronary artery disease. Additionally, the identification of another medical condition called Metabolic Syndrome further establishes the relationship between obesity and elevated triglycerides. This syndrome is considered an independent cardiac risk factor, equal in importance to and in some cases a precursor for other well established risks, such as diabetes, hypertension, and previous myocardial infarction. The syndrome is present in up to 47 million Americans. Its components include:

- Waist circumference greater than 40 inches (35 inches in women)
- Serum triglyceride level > 150 mg/dL
- HDL < 40 mg/dL in men and 50 mg/dL in women.

- Blood pressure of 130/85 mm Hg or higher
- Fasting glucose level of 110 mg/dL or higher

When looking specifically at cardiac risk factors, despite tremendous gains in understanding the etiology, treatment and prevention of coronary heart disease, we have made only modest gains in preventive risk reduction. Only 3-10% of individuals in the United States and Europe currently fall within the guidelines of having low risk profiles, even though reaching these goals would result in a 80-90 percent reduction in coronary events, coronary vascular disease mortality and could increase life span by an estimated six to ten years.

Looking beyond coronary disease, in the last year alone, the failure to provide a viable solution to the obesity epidemic has spawned approximately 120,000 obesity-related surgical treatments.

Clearly the challenge to all of us involves:

- Recognizing obesity as a public health issue;
- Realizing that the solution must be safe, effective and practical and may not come in "one size fits all"; and finally
- Remaining open to new approaches supported by emerging research.

A Different Solution to Combating Obesity

The traditional dietary establishment has recommended nutritional guidelines that have failed to curb the growing epidemic of obesity. Although this is likely the result of a combination of external factors related to lifestyle that impact energy consumption and expenditure, the message of caloric control and fat reduction has not produced the anticipated reduction in the rising rate of obesity that was expected.

Experts agree that the solution is NOT to be found in a particular diet, but rather a modification of lifestyle risk factors for obesity. These would include dietary modifications combined with exercise to reach long term net health gains.

Atkins represents just this type of intervention, focusing on educating individuals to make intelligent food choices favoring nutrient dense whole foods in a way that includes adequate protein and fat which provides satiety and satisfaction and improves compliance. By shifting attention from calorie counting, portion control, and fat reduction, Atkins teaches individuals how to make better selections while at the same time address other significant health risks through exercise.

The Atkins Nutritional Approach (ANA) is a scientifically validated strategy for weight control and good health based upon controlling carbohydrates. The ANA stresses nutrient dense carbohydrates as part of a balanced eating plan that includes proteins and good fats while restricting carbohydrates with the greatest

impact on blood sugar. The ANA provides each person with the knowledge and tools including four phases of Atkins to optimize their health and find their individual level of carbohydrate intake below which weight loss is achieved and above which weight gain occurs.

The Atkins Lifestyle approach provides a number of options since everyone's metabolism and lifestyle are different. Atkins is about choosing carbohydrates wisely by focusing on fiber rich vegetables, fruits, legumes and whole grains – while avoiding refined carbohydrates and foods with added sugar. And while bacon is one protein option, the Atkins approach includes poultry, fish, lean pork, beef and soy products. Healthy fats from vegetable and seed oils, cheese and dairy, nuts and legumes round out the approach.

Over the past seven months, my colleagues on the Atkins Physicians Council and I have met with government policy makers on nutritional and health issues, and have developed the Atkins's Lifestyle Food Guide Pyramid to clarify myths and misconceptions about the Atkins Nutritional Approach (see attachment). Unlike the government's food pyramid, the Atkins approach reflects the tenets of ANA and illustrates its guide to a healthy lifestyle. The pyramid displays the importance of physical activity within the graphic, reflecting the dynamic relationship between activity level and food consumption, eliminates added sugar and hydrogenated oils from the diet, and stresses food choices based on proteins and nutrient-dense vegetables and other whole foods.

Atkins is a personalized approach to identifying a level of carbohydrate consumption that is consistent with achieving ideal body weight that can then be maintained for a lifetime of improved health. Simple, straightforward and safe, controlled carbohydrate nutrition offers a scientifically validated solution to the challenge of weight reduction and maintenance, and one that can help many people meet their weight management goals.

Scientific Support for Controlled Carbohydrate Nutrition

The scientific evidence supporting controlled carbohydrate nutrition dates back many years, with reports from as early as 1972 (Young et al. J. Clinical Nutrition) demonstrating that lowering carbohydrate consumption significantly reduces body fat even when calories are maintained equal (1800 calories).

Even in adolescents fed more calories (1100 vs. 1830), work by Sondike has demonstrated that more weight is lost with low carbohydrate intake as compared with low calorie/low fat approaches. More recently studies completed at Duke University under the direction of Dr. Eric Westman confirmed greater weight loss at six months with a low carbohydrate program, approximately twice that seen with a traditional low fat approach (30 versus 18 lbs). Work supported by the American Heart Association and performed by Bonnie Brehm, MD, looking at 53

obese women over a three year period showed that more weight (8.5 ± 1.0 vs. 3.9 ± 1.0 kg; $p < 0.01$) and more body fat (4.8 ± 0.67 vs. 2.0 ± 0.75 kg; $p < 0.01$) were lost on a low carbohydrate diet than on a low fat/low calorie program. Insulin and glucose levels also improved on Atkins, diminishing the risks of developing diabetes.

In the past two years there have been even more articles published in medical, peer reviewed journals, with the total now at 28 in the last three years. Included in this list are publications in The New England Journal of Medicine (Foster et al), the Journal of the American Medical Association (Stern et al) and most recently in the May 18, 2004 issue of the Annals of Internal Medicine (Yancy et al from Duke University and Stern et al from the Philadelphia V.A. Medical Center). These studies have shown that by limiting carbohydrates, individuals on average demonstrate equal or greater weight loss (statistically significant through the first six months) than that seen with traditional recommendations, without any clinical evidence of increased cardiovascular or metabolic risk identified. These studies contain follow-up through 12 months, and in at least one case, in a multi-center study funded by the NIH, individuals are being followed prospectively for a total of two years.

Within these studies, laboratory analysis of established serum risk factors for coronary artery disease demonstrate on average consistent reduction of triglyceride levels, as well as improvement in the HDL (good cholesterol) without significant increase observed of either total or LDL cholesterol. In Dr. Westman's work at Duke University, an eight-fold improvement in the TG/HDL ratio was recorded. A separate study completed by Dr. Jeff Volek has demonstrated that for individuals followed on a controlled carbohydrate nutritional program, post-prandial lipemia, as measured as circulating TAG, is actually seen to decrease, as well as fasting TAG. These are both important measures of coronary heart disease. Studies have also demonstrated a reduction in measures of inflammation recently hypothesized to play an important role in the development of coronary artery disease – as measurement by levels of C-reactive protein (O'Brien et al and Volek et al), and in diabetic control (Stern et. al.) when following this strategy.

Mechanism of Action

The principals of this approach involve modifying the metabolic pathways in which energy is used to encourage the oxidation of stored fat for fuel, while at the same time minimize the storage of excess calories within the body as fat. These goals are achieved with the Atkins Nutritional Approach by limiting carbohydrate intake, through a four phase program. This program is designed to help individuals effectively manage carbohydrate cravings initially and to maximize long term success through the transition to a lifetime strategy that involves reintroducing nutrient dense whole foods with complex carbohydrates to

identify a personalized carbohydrate threshold. (Richard D. Feinman, PhD and Eugene J. Fine, MD, "Thermodynamics and Metabolic Advantage of Weight Loss Diets," *Metabolic Syndrome and Related Disorders*, Vol. 1, No. 3 (2003))

From a physiologic perspective, controlled carbohydrate nutrition relies on the lipolysis or breakdown of stored fat for fuel. Although this pathway is ordinarily a secondary method of providing energy, by limiting the availability of carbohydrates it can readily become the primary mechanism and in doing this, has been shown to result in improved energy levels, elevated mood, as well as lessened cravings, heartburn, and premenstrual symptoms (Westman). This is all while allowing people to consume satisfying good tasting food in ample portions and lose weight.

Inherent in the conversion and support of this metabolic pathway for long term maintenance, and the reintroduction of healthy carbohydrates into the diet is an understanding of recent science that has demonstrated that when it comes to impacting blood sugar (glucose) levels, not all carbohydrates are created equally. Specifically, it is the amount and rate of rise in blood sugar levels that is important here, concepts referred to glycemic index (GI) and glycemic load (product of GI X total grams).

Because not all carbohydrates are digested, (i.e. fiber), their impact on blood sugar levels is lessened. Similarly there are certain other carbohydrates, like sugar alcohols that do not raise blood sugar levels significantly and therefore provide taste and flavor to foods without the resultant impact on blood sugar levels. These do not result in the insulin spikes that occur when other blood sugar raising carbohydrates are consumed. Since insulin interferes with the breakdown of fat, and also is involved with the storage of excess calories as body fat, the minimization of the modulation of this hormone through dietary choices plays a key role in controlled carbohydrate nutrition.

Several investigators have suggested that the apparent metabolic advantage that has been demonstrated in studies (i.e. Sondike et al, as well as Green et al from Harvard University) that show individuals can lose more weight while consuming a greater total amount of calories when carbohydrates are limited have suggested this may be related to the increased metabolic demands associated with the macronutrient breakdown and resynthesis of glucose through the process of gluconeogenesis (formation of new glucose) that takes place when carbohydrates are limited. Others have suggested that the presence of ketones, or components of the diet itself may increase satiety and help reduce total caloric consumption. Regardless of the mechanism, there has been sufficient evidence to demonstrate the weight loss, and predominantly body fat loss does occur while following a controlled carbohydrate program, even without caloric restriction.

Long Term Benefits of Controlled Carbohydrate Nutrition

Peer reviewed studies conducted for up to one year have shown that not only is a controlled carbohydrate approach with an increase in protein intake safe and effective, but it has health benefits.

Two studies in the May 18, 2004 issue of the Annals of Internal Medicine provide further evidence that a controlled carbohydrate approach can on average significantly improve cholesterol levels, in contrast to concerns that this strategy would cause the opposite. In a short term Duke University study (Yancy et. al.) people were randomly assigned to a low-carbohydrate or a low-fat, low-cholesterol, reduced-calorie diet for 24 weeks. Compared to the low-fat diet, patients in the low-carbohydrate diet lost more weight, had a greater decrease in triglyceride levels - blood fats that can raise the risk of heart attack or stroke – and had higher-density lipoprotein (HDL) levels, the so-called “good” cholesterol.

In the Stern et al study from the Philadelphia V.A. Medical Center, researchers looked at severely obese adults on low-carbohydrate and conventional low-fat diets. After one year, the researchers found that those on the low-carbohydrate diet had more favorable triglyceride and high-density lipoprotein cholesterol levels and better diabetes control. While in both studies dieters following the Atkins nutritional approach lost more weight at the end of six months than people on a low-fat diet, by 12 months, the weight loss of both groups was similar.

As more research is conducted, Atkins is continuing to demonstrate safety and efficacy in peer reviewed study after study, and for this reason should now be seen as a clear and viable alternative to not only weight loss, but maintaining a healthy lifestyle. Unlike fad diets, cumulated scientific research has shown how the reduced carbohydrate approach is a valid nutritional strategy.

Controlled Carbohydrate Nutrition and the Federal Dietary Guidelines

It is difficult to determine if the current popularity of controlled carbohydrate nutrition stems from the realization, that as explained by Walter Willett of the Harvard School of Public Health “mainstream nutritional science has demonized dietary fat, yet 50 years and hundreds of millions of dollars of research have failed to prove that eating a low fat diet will help you live longer.” It could be that three decades of a national campaign to reduce fat intake has done nothing to combat the rise of obesity in this country (CDC/NCHS).

In light of the emerging science that supports the safety and efficacy of controlled carbohydrate nutrition, recognizing the reasons why, by some estimates, 35 million Americans are currently following this strategy is extremely important. It may also offer a significant clue in solving this country’s obesity

problems. With enthusiasm for weight loss and improved health through nutrition rekindled, it is time to work together to build rather than destroy. At the very least, we need to recognize that our population is not satisfied with the dietary recommendations they have been given. Quoting again from Dr. Willett, "we can no longer dismiss very low-carbohydrate diets."

Counting carbohydrates is quite simply easier for many people than eating smaller amounts of less satiating foods. This empowerment serves as a cornerstone of controlled carbohydrate nutrition, and fosters a renewed interest in making educated food choices that many find extremely gratifying. This is especially true for the many who have been unsuccessfully managing their weight through standard recommendations, who now feel able to take control, and to improve their health by managing their carbohydrates ... in contrast to struggling with portion control and unsatisfying cuisine.

As the science in support of controlled carbohydrate diets continues to mount, it is important for all the policymakers involved in revisiting the national dietary guidelines not to ignore this evidence and recognize the role this strategy can have in impacting the epidemic.

Any revision of the guidelines should incorporate some of the Atkins Nutritional Principles such as:

- Consuming an adequate balance of protein (at least 30 to 35% of total calories) to provide satiety and increased thermogenesis
- Incorporating a balance of untreated fats in adequate amounts to provide satiety and meet nutritional needs
- Teaching carbohydrate awareness so that Americans learn to respect and understand which carbs are the most nutrient dense and which are high or low glycemic index.
- Identifying the individual level of carbohydrate intake under which weight loss is achieved and over which weight gain occurs.

Conclusion

We are in a unique situation, having learned much from well controlled research studies that have identified actual health benefits rather than risks associated with following the controlled carbohydrate nutritional strategy. We have also seen a growing number of people show renewed interest in how what they eat impacts their health. If providing unrealistic goals has led to apathy, and non-specific recommendations have led to misinterpretation, the time is right to rely on evidence based in science to develop strategies to effectively have an impact on this crisis. If more research is needed, let's fund it. It's hard for me to imagine any other public health crisis more important than those I've outlined for you today.