

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

FDA OBESITY WORKING GROUP

+ + + + +

FDA PUBLIC MEETING ON OBESITY

+ + + + +

THURSDAY,

OCTOBER 23, 2003

+ + + + +

The meeting was convened in the Jack Masur Auditorium at the National Institute of Health, Bethesda, Maryland at 9:00 a.m., LESTER M. CRAWFORD, D.V.M., Ph.D., Chair, presiding.

PRESENT:

LESTER M. CRAWFORD, D.V.M., Ph.D.  
Deputy Commissioner of Food and Drugs  
Chair, FDA Obesity Working Group

MIKE LANDA  
Deputy Chief Counsel, FDA

JOSEPH LEVITT  
Vice Chair, FDA Obesity Working Group  
Director, Center for Food Safety and Applied Nutrition

DAVID G. ORLOFF, M.D.  
Director, Division of Metabolic & Endocrine Drugs  
Center for Drug Evaluation and Research, FDA

PETER J. PITTS  
Associate Commissioner, Office of External Relations,  
FDA

ALAN J. RULIS, PH.D.  
Senior Advisor for Applied Nutrition  
Center for Food Safety and Applied Nutrition, FDA

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

## I-N-D-E-X

AGENDA PAGE	ITEM
WELCOME 3	
Lester M. Crawford, D.V.M., Ph.D.	
KEYNOTE 7	ADDRESS
Tommy G. Thompson Secretary of Health and Human Services Department of Health and Human Services	
Cristina V. Beato, 24	M.D.
Acting Assistant Secretary for Health Department of Health and Human Services	
OPENING 10	ADDRESS
Mark B. McClellan, M.D., Ph.D. Commissioner, FDA	
INTRODUCTION 33	OF FDA PANEL
OVERVIEW OF THE FDA OBESITY WORKING GROUP 34	
OPENING 34	REMARKS
Lester M. Crawford, D.V.M., Ph.D.	
OVERVIEW 36	
Alan Rulis, Ph.D.	
BUILDING A KNOWLEDGE BASE ABOUT OBESITY 46	
Donna Robie Howard, Ph.D. Special Assistant to the Senior Advisor for Applied Nutrition; Center for Food Safety and Applied Nutrition, FDA	
Rick Canady, 67	Ph.D., DABT
Senior Science Policy Analyst Office of Science and Health Coordination, FDA	
HIGHLIGHTS AND	SUMMARY

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2724

77  
Joseph A. Levitt

PUBLIC PARTICIPATION SESSION  
81  
Moderated by Joseph Levitt

OPEN DISCUSSION  
276

CONCLUSION AND NEXT STEPS  
279

P-R-O-C-E-E-D-I-N-G-S

(9:11

a.m.)

WELCOME

CHAIRMAN CRAWFORD: I want to welcome

all

of you to the public meeting on obesity. I am Les Crawford, Deputy Commissioner of the Food and Drug Administration. I am also Chair of the FDA Obesity Working Group, the group that is sponsoring today's meeting.

When Commissioner McClellan asked us to chair the working group in August of this year, one of the major charges he gave to us was to initiate a dialogue with the many organizations and individuals who are concerned about obesity.

The need to confront the epidemic of overweight and obesity, which now includes almost two-thirds of our population, is very likely to be with us for the next several years. And it may well bring about important regulatory innovations.

Today's meeting is the first of many

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 discussions that we will have as we work together  
2 over  
3 the years to meet the many challenges presented by  
4 this very serious public health problem.

5 We hope to learn more about our efforts  
6 to  
7 help Americans to improve their diets, to make  
8 healthy  
9 choices, and to exercise. We're also interested in  
10 exploring your views and insights on the six focus  
11 areas that form the foundation of our dialogue.  
12 These  
13 are education, research, therapeutic treatments,  
14 food  
15 labeling, product research and development, and  
16 significant opportunities for FDA to make a  
17 difference  
18 in confronting the epidemic of overweight and  
19 obesity.

20 You are a very diverse and capable  
21 audience today representing food and pharmaceutical  
22 firms and trade associations, leading consumer  
23 organizations, the research and academic  
24 communities,  
25 medical and voluntary health organizations, the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 media,  
2 consulting firms, our international colleagues, law  
3 firms, state government agencies, and associated  
4 organizations, and organizations that educate  
5 consumers about how to adopt healthy lifestyles.

6 The federal government is also  
7 well-represented, including all of the HHS  
8 agencies,  
9 the Office of the Surgeon General, FDA, the  
10 National  
11 Institutes of Health, Health Resources and Services  
12 Administration, the Agency for Health Care Research  
13 and Quality, as well as the many key offices of the  
14 U.S. Department of Agriculture, the Federal Trade  
15 Commission, and the Library of Congress.

16 I would especially like to recognize  
17 the  
18 efforts of my fellow HHS agencies for the support  
19 and  
20 outstanding efforts that they are undertaking to  
21 work  
22 with us to confront obesity. I would like to  
23 recognize these efforts and briefly introduce to  
24 you  
25 the leadership of these agencies.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 I would ask that they please stand and  
2 remain standing. And if we could hold our applause  
3 until the end? The first is Rear Admiral Dr.  
4 Moritsugu, the Deputy Surgeon General. Dr.  
5 Cristina  
6 Beato, the Acting Assistant Secretary for Health,  
7 will  
8 be with us a bit later; Dr. Robert Graham, the  
9 Acting  
10 Deputy Director, Agency for Health Care Research  
11 and  
12 Quality; Elizabeth Majestic, Acting Deputy  
13 Director,  
14 National Center for Chronic Disease Prevention and  
15 Health Promotion, Center for Disease Prevention and  
16 Control; and Dr. Susan Yanovski, Director, Obesity  
17 and  
18 Eating Disorders Program, National Institute of  
19 Diabetes and Digestive and Kidney Disease.

20 I would also like to thank Tracy Self  
21 and  
22 ask her to stand -- she's the Assistant Secretary  
23 for  
24 Public Affairs -- and Stacey Maazer, Special  
25 Assistant

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 to Dr. Beato, for being with us here today. If we  
2 could, applause?

3 (Applause.)

4 CHAIRMAN CRAWFORD: We are enthused  
5 about  
6 today's meeting. And we look forward to hearing  
7 the  
8 diversity of views that are represented by  
9 participants. Our agenda is full, and time is  
10 limited. So, again, we welcome you. And let's  
11 begin  
12 our meeting.

13 At this point, Secretary Thompson has  
14 taped a message for us. He was unable to be here  
15 in  
16 person, but he has taped remarks so that he could  
17 be  
18 a part of our meeting today.

19 Before running the tape, I would like  
20 to  
21 say a few words of introduction. We are very  
22 privileged to have Secretary Tommy Thompson join us  
23 as  
24 we begin our dialogue on what efforts FDA can take  
25 to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrsgross.com



1 confront obesity.

2 Secretary Thompson is a leading voice  
3 in  
4 the United States bringing the message of  
5 prevention  
6 in the communities everywhere. He's, in fact, the  
7 face of disease prevention in America.

8 Obesity, especially obesity in  
9 children,  
10 is a special concern for the secretary, as you will  
11 see in a moment, particularly when you recognize  
12 the  
13 devastating impact that obesity can have on the  
14 health  
15 and well-being of Americans and their families.

16 Secretary Thompson has challenged HHS  
17 agencies to intensify our efforts and follow his  
18 leadership in taking action to help consumers to  
19 improve their diets, to make healthy choices, and  
20 exercise. It is this challenge that brings us here  
21 today.

22 Following the secretary's remarks, Dr.  
23 Cristina Beato will address the meeting. Dr. Beato  
24 is  
25 the Acting Assistant Secretary for Health. She

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 leads  
2 HHS efforts to reduce health disparities to combat  
3 HIV/AIDS, to encourage prevention strategies, to  
4 reduce chronic diseases, and to advance women's  
5 health.

6 Now, if we could have the tape at this  
7 point?

8 KEYNOTE ADDRESS

9 MR. THOMPSON: Hello. I'm Tommy  
10 Thompson,  
11 the Secretary of Health and Human Services. I am  
12 so  
13 pleased to be able to send greetings to all of my  
14 friends attending the FDA's obesity workgroup  
15 meeting.

16 I would like to thank Dr. McClellan and Dr.  
17 Crawford  
18 for hosting this very important meeting.

19 As some of you have discussed with me  
20 last  
21 July in my obesity roundtable meeting, we Americans  
22 are increasingly supersizing ourselves and our  
23 nation.

24 Unfortunately, this trend continues to grow.

25 Today every state except Colorado has

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 an  
2 obesity rate higher than 15 percent. And obesity  
3 is  
4 the second leading cause of preventable deaths in  
5 the  
6 United States, accounting for more than 300,000  
7 deaths  
8 each year and costing American taxpayers up to \$117  
9 billion in direct and indirect costs.

10 Overweight and obese people have a much  
11 higher chance of developing Type II diabetes, heart  
12 disease, certain cancers, high blood pressure, high  
13 cholesterol, and other ailments.

14 The challenge that lies ahead is  
15 formidable but one that all of us must address. I  
16 have taken action by launching an initiative for  
17 improving health through the steps to a healthier  
18 U.S.

19 I have asked each division of the  
20 Department of Health and Human Services to be able  
21 to  
22 prioritize disease prevention and health promotion  
23 initiatives. We have the opportunity to improve  
24 the  
25 health of more Americans than ever before. And I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 think it is critical that we do as much as possible  
2 to  
3 meet this challenge.

4 I applaud Mark and Les and the staff at  
5 FDA for doing this part in addressing this very  
6 important issue. And I am so very grateful to all  
7 of  
8 you for all of the work that you have already done  
9 on  
10 obesity.

11 I look forward to continuing to work  
12 with  
13 you in the future. God bless you. God bless the  
14 United States of America.

15 (Applause.)

16 CHAIRMAN CRAWFORD: It is now my  
17 distinct  
18 pleasure to introduce to you FDA Commissioner Mark  
19 McClellan. Dr. McClellan is the moving force  
20 leading  
21 the agency in its efforts to make a significant  
22 difference in addressing the obesity epidemic.

23 Within the past year, Dr. McClellan has  
24 charted an aggressive course to begin building the  
25 foundation needed to address the problem of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrgross.com

1 obesity.

2 Some of these efforts include working with the  
3 agency's executive leadership to establish our  
4 strategic plan, which will complement and  
5 strengthen  
6 our efforts as we go forward to confront the  
7 obesity  
8 challenge, providing consumers with better  
9 nutrition  
10 information by allowing the labeling of food  
11 packages  
12 with qualified health claims, and working with the  
13 administration on aging and the National Alliance  
14 for  
15 Hispanic Health to provide elderly Hispanic  
16 consumers  
17 and their care-givers with important health  
18 information.

19 Under his leadership, we now have the  
20 opportunity through the FDA Obesity Working Group  
21 to  
22 strengthen and expand our efforts to support  
23 consumers  
24 in their efforts to be healthy, improve their  
25 diets,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 and be physically active. It is my pleasure to  
2 introduce FDA Commissioner Mark McClellan.

3 (Applause.)

4 DR. McCLELLAN: Thank you, Les. And  
5 thanks to all of you for being here.

6 OPENING ADDRESS

7 DR. McCLELLAN: I want to particularly  
8 commend Les Crawford and his coconspirator in this  
9 effort, Mr. Joe Levitt from our Center for Food  
10 Safety  
11 and Applied Nutrition, for their leadership in  
12 moving  
13 this task force. I also want to thank Dr. Alan  
14 Rulis,  
15 who has been instrumental in this and many other  
16 activities on applied nutrition. Dr. Christine  
17 Taylor  
18 I think will be here soon as well.

19 Les mentioned something about me being  
20 a  
21 moving force. Actually, one of the things you  
22 learn  
23 when you run an agency is that you don't move much  
24 of  
25 anything by yourself, that things only happen as a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrgross.com

1 result of the commitment and dedication and  
2 professionalism of the workforce in the agency.  
3 And  
4 that is nowhere more true than at FDA, where we  
5 don't  
6 give out a lot of grants, we don't deliver a lot of  
7 health services.

8 It really is the people at the agency  
9 that  
10 make all of the difference for public health. And  
11 I  
12 have been tremendously impressed by the leadership  
13 throughout the agency to help take on this new and  
14 important challenge of obesity in our country.

15 The Obesity Working Group is charged  
16 with  
17 a difficult task, but I think with Joe and Les at  
18 the  
19 helm and with the backing of our professional staff  
20 at  
21 FDA, I know we will make important steps in  
22 advancing  
23 the public health.

24 On behalf of FDA, I would also like to  
25 offer my appreciation for the deep commitment of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 Secretary Tommy Thompson to take on this urgent  
2 public  
3 health issue. As you just heard again from the  
4 secretary, he is passionate about the issues that  
5 we  
6 are here to discuss today.

7 And so is my good friend Dr. Cristina  
8 Beato. I want to thank her for helping to bring  
9 disease prevention to the forefront of the national  
10 public health agenda.

11 Dr. Richard Carmona, our nation's  
12 Surgeon  
13 General, who is out traveling today, has also been  
14 an  
15 instrumental part in our efforts to improve the  
16 nation's health literacy and to take on obesity.  
17 He  
18 is represented here very ably by Admiral Moritsugu.  
19 I want to thank the admiral for his assistance in  
20 all  
21 of these efforts as well as Admiral Graham, here  
22 from  
23 the Agency for Health Care Research and Quality.

24 And, as Les mentioned, our hosts in  
25 this

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1 auditorium here at NIH have been important partners  
2 and contributors to this effort, as has Dr. Julie  
3 Gerberding and the staff of the CDC.

4 I especially want to thank all of you,  
5 the  
6 academic experts, the consumer organizations, the  
7 health professionals, the education experts and  
8 leaders, the government groups, and, most  
9 importantly,  
10 the interested public who are participating in this  
11 effort here today.

12 Healthy living and healthy choices for  
13 disease prevention are a top priority for the  
14 Department of Health and Human Services, helping  
15 more  
16 Americans achieve a healthy weight is a top  
17 priority  
18 for all of us working on the nation's public health  
19 problems.

20 That's for a simple reason. Quite  
21 simply,  
22 obesity is an urgent public health threat of  
23 epidemic  
24 proportions. Today, nearly two-thirds of all  
25 Americans are overweight. And more than 30 percent

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 are obese.

2           The rising incidence of obesity and  
3 oversight has dramatic consequences for our health,  
4 as  
5 you heard from Secretary Thompson and others:  
6 heart  
7 attacks, heart failure, high blood pressure,  
8 respiratory problems, arthritis, many cancers. The  
9 list is long. The list is sobering.

10           The trends for our children are  
11 particularly worrisome. Recent research from the  
12 Centers for Disease Control shows that about 13  
13 percent of children age 6 to 11 are overweight,  
14 almost  
15 double the rate of 2 decades ago. Increasingly,  
16 diseases that were once thought to go along with  
17 older  
18 ages, such as Type II diabetes, are occurring in  
19 children.

20           The issue of obesity challenges us in  
21 every aspect of our efforts to protect and advance  
22 the  
23 public health. And that's why it needs to be front  
24 and center on our public health agenda.

25           And so we are taking some new steps at

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 FDA  
2 to help people improve their health by avoiding  
3 obesity. Improved nutrition labeling, new steps to  
4 encourage foods that compete based on their health  
5 consequences. Other steps I'm going to tell you  
6 more  
7 about in just a few minutes because I would like to  
8 build on them.

9 We need to do more. FDA has a big role  
10 to  
11 play in this effort, in education of the public,  
12 about  
13 public health problems in labeling and information  
14 about foods, both foods in the grocery stores and  
15 foods that we eat out, in helping to make available  
16 safe and more nutritious foods and diet choices, in  
17 promotion of foods, advertising, and labeling  
18 promotion of their health consequences, in such  
19 emerging areas as nutrigenomics in developing  
20 medical  
21 products for obesity. The list is long. And to  
22 make  
23 sure that we are taking a comprehensive approach to  
24 these problems, we formed a working group at FDA to  
25 find new and innovative ways, the best ways to help

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 people lead healthier lives through better  
2 nutrition.

3 I've asked this working group to come  
4 up  
5 with a report by February that includes a specific  
6 action plan for setting out our further  
7 comprehensive  
8 efforts to combat obesity. Some of the  
9 opportunities  
10 that are available include further research and  
11 efforts to define healthy diet choices, new  
12 opportunities to aid in the development of  
13 therapeutic  
14 treatments, medical treatments for obesity,  
15 possible  
16 further changes to the food label, and a serious  
17 dialogue already underway with industry, including  
18 the  
19 restaurant industry, on how we can work together to  
20 help people follow healthier diets.

21 We have a pretty good idea of what's  
22 behind the trends of the last decades that  
23 Secretary  
24 Thompson talked about. In recent years, we have  
25 seen

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 an imbalance in people's dietary choices between  
2 calories in and energy out. And even a slight  
3 imbalance of just 100 calories on a daily basis  
4 over  
5 a long time period can add up to many, many pounds  
6 of  
7 excess weight and excess health risks over time.

8 We live in a wealthy society, but we  
9 are  
10 time-poor. We often turn to foods for convenience.  
11 Sometimes these foods are high in fat and sugar.  
12 If  
13 they're used disproportionately in our diet, it can  
14 add up, add up in that calorie burden.

15 Exercise is not an automatic part of  
16 everyday living for many Americans. Fewer people  
17 are  
18 sharing the fun of playing exercise with their  
19 children on a daily basis. We need to get our kids  
20 out from in front of the television and onto the  
21 playground.

22 We have seen a lot of progress in food  
23 production. Food is cheaper. It's easier to  
24 prepare.  
25 It's more plentiful than ever before. It also

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 tastes  
2 better. And those are valuable steps forward for  
3 helping Americans live better lives.

4 The bottom line is that as our lives  
5 are  
6 getting easier and richer in so many ways, we must  
7 work harder and think more about our lifestyle and  
8 about the lifestyle and well-being of our children.

9 We clearly need more innovation to help  
10 people choose a diet that is not only easier to  
11 prepare and better tasting and more economical but  
12 also better for their health.

13 As Dr. Crawford mentioned, FDA is  
14 making  
15 major strides to improve food safety and nutrition  
16 and  
17 to address this growing health trend. And the  
18 Obesity  
19 Working Group is a milestone in that effort. We're  
20 also working on other initiatives to help address  
21 this  
22 urgent public health need.

23 A well-informed public is one of the  
24 best  
25 weapons against some of our biggest public health

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 problems. Better information means that consumers  
2 can  
3 make better choices. And some of the most  
4 important  
5 health choices that people make today are about the  
6 foods they choose to eat.

7 So one of our most important tasks at  
8 FDA  
9 is to help ensure that Americans can rely on the  
10 information they receive to make smart decisions  
11 about  
12 food, decisions that should be based on the latest  
13 up-to-date accurate scientific information, the  
14 growing amount of scientific information on how  
15 dietary choices can influence our health.

16 So people need good clear information  
17 about the nutritional value of their foods. They  
18 also  
19 need to be protected from misleading information.  
20 We  
21 need fewer snake oil claims that create false hopes  
22 and can get in the way of improving health and more  
23 olive oil and vegetable oil claims where the  
24 scientific evidence shows that substituting  
25 products

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

1 like these that are high in unsaturated fats for  
2 other  
3 food products, high in saturated and trans fats,  
4 may  
5 reduce the risk of heart disease, just to give you  
6 one  
7 example.

8                   In July, we announced a major change,  
9 the  
10 first change in a decade, on the nutrition label on  
11 foods to include a separate listing of trans fats.  
12 And we tend to pursue even more changes in the  
13 months  
14 ahead to make sure that the nutrition label is as  
15 useful as possible for people to follow a healthy  
16 diet.

17                   Our task force on consumer health  
18 information for better nutrition, which issued its  
19 final report in July, was charged, among other  
20 things,  
21 with developing an FDA-regulated and overseen  
22 process  
23 to help consumers get more accurate information  
24 about  
25 the health consequences of their food choices.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com



1                   The FDA believes that the process for  
2 making science-based health claims when combined  
3 with  
4 our strong enforcement work will help people choose  
5 healthier products while protecting them from  
6 companies that make false or misleading claims and  
7 will create an environment that encourages and  
8 rewards  
9 companies for helping develop foods that help  
10 consumers follow a healthy diet and reduce the  
11 problems of obesity and other chronic illnesses.

12                   In order to provide the right  
13 incentives,  
14 in order to make short-term improvements in the  
15 foods  
16 already on the market, it's not enough simply for  
17 us  
18 to determine that foods are safe. We need to take  
19 steps to encourage food producers to make truthful  
20 science-based claims about the health benefits of  
21 their products.

22                   So the end result we hope will be  
23 innovation that we most desperately need,  
24 innovation  
25 in foods and in diets that are easier to follow,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 that  
2 offer good nutrition, and that help consumers  
3 achieve  
4 healthy weights. Having better informed consumers  
5 will go a long way towards disease prevention. But  
6 it's not enough as a solution to the problem of  
7 obesity.

8 We also need to do more to translate  
9 good  
10 ideas and research into safe and effective  
11 treatments  
12 for patients. Today too many people who are  
13 worried  
14 about losing weight focus on dietary supplements  
15 that  
16 might help them lose weight, at least in the short  
17 term, but that also appear to carry important  
18 increased risk, such as higher blood pressure and  
19 serious adverse health events. People sometimes  
20 even  
21 turn to cigarettes, our number one cause of  
22 preventable illness in this country. So we need to  
23 do  
24 better.

25 Science and technology as well as

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 individual choices can improve, especially when our  
2 public policy is focused on encouraging desirable  
3 changes. Far fewer people are smoking today than a  
4 couple of decades ago, more exercising on their  
5 own,  
6 and far more are eating diverse and potentially  
7 healthy diets than they did just a few decades ago.  
8 We need to bring that same effort to the problem of  
9 obesity and overweight.

10 I mentioned before that it's just an  
11 imbalance of 100 calories a day that can make the  
12 difference over a long time period. If we can work  
13 together to find ways to help people shift that  
14 balance just a little bit, 100 or 200 more calories  
15 a  
16 day of exercise out, 100 or 200 fewer calories of  
17 food  
18 intake in, and we're on a completely different  
19 trajectory if we can find ways to help all  
20 Americans  
21 participate in this change.

22 We have learned over and over again  
23 that  
24 behavior can change, that people will choose to  
25 lead

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

1 better lives when we give them the knowledge, the  
2 education, coupled with the accurate and compelling  
3 information they need, and coupled with better  
4 choices, better products to help them achieve the  
5 goals that matter to them. And that's why we're  
6 here  
7 today.

8 I would like to spend a minute talking  
9 about the key questions that we have asked this  
10 public  
11 meeting to address and that we hope will engage all  
12 of  
13 you in giving us your best and latest ideas.

14 The first question, what is the  
15 available  
16 evidence on the effectiveness of various education  
17 campaigns to reduce obesity? There are a lot of  
18 programs going on now, thanks to the growing  
19 interest,  
20 both nationally and at the local level, in the  
21 public  
22 and private sectors in addressing this problem.  
23 What  
24 do we know about what works? How can we help get  
25 those education messages out?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1                   Second, what are the top priorities for  
2 nutrition research to reduce obesity, particularly  
3 to  
4 reduce obesity in children? What can we do to  
5 improve  
6 the nutrition guidance that we provide and the  
7 diets  
8 that we give our children so that we can address  
9 that  
10 most worrisome problem of increasing obesity and  
11 overweight among young people, a problem that might  
12 stay with them for the rest of their shorter, less  
13 healthy lives?

14                   What is the available evidence? Third  
15 question, what is the available evidence that the  
16 FDA  
17 can look to in order to provide effective public  
18 efforts to prevent and treat obesity by behavioral  
19 or  
20 medical interventions or combinations of both?

21                   We have made clear at the FDA that we  
22 want  
23 to encourage better development of medical  
24 treatments,  
25 better products. And we are developing a guidance

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 for  
2 product developers in this effort, to show them a  
3 clear pathway to bringing these products to the  
4 public, safe and effective products, which, as I  
5 mentioned before, we don't have enough of today.  
6 What  
7 is the available evidence to help us in that  
8 effort?

9 Fourth, are there changes needed to  
10 food  
11 labeling that could result in the development of  
12 better, healthier, lower-calorie foods and the  
13 selection of healthier, lower-calorie diets by  
14 consumers? What can we do through the food  
15 labeling  
16 process?

17 Fifth, what opportunities exist for the  
18 development of healthier foods and diets? And what  
19 research might best support the development of  
20 healthier foods? There's been a tremendous amount  
21 of  
22 innovation in the food industry, as I mentioned  
23 before, that has made Americans much better off  
24 through easier to prepare, more diverse, and lower  
25 cost foods than at any time in the history of the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 world. What else can we do to help bring that kind  
2 of  
3 innovation to developing healthier diets, to make  
4 healthier diets more attractive for people to  
5 follow?

6 And, finally, sixth, based on the  
7 scientific evidence available today, what are the  
8 most  
9 important things that FDA can do to make a  
10 significant  
11 difference in efforts to address the problem of  
12 overweight and obesity.

13 We've got a big mission at FDA:  
14 protecting and advancing the health of the public.  
15 We're charged with regulating close to a quarter of  
16 the consumer economy and assuring the safety and  
17 effectiveness of some of the most personal products  
18 that people use to impact their health.

19 We've got limited resources to address  
20 those problems, a very dedicated staff, over 10,000  
21 highly dedicated professionals out there helping us  
22 fulfill this mission every day, but we can't do  
23 everything.

24 We need to know where we can best focus  
25 our efforts to address this top priority public

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 health  
2 problem. And we need your help in addressing this  
3 problem.

4 So those are the questions that we hope  
5 will focus a lot of the discussions today. We  
6 welcome  
7 to hear from you on any ideas that you have where  
8 FDA's mission intersects with this important public  
9 health goal.

10 The public health challenges are great,  
11 but the opportunities to make a real difference for  
12 the health of the public have never been greater  
13 than  
14 in the case today in terms of addressing the  
15 problem  
16 of obesity.

17 I want to thank you all again in  
18 advance  
19 for your help in working with us on this important  
20 problem on behalf of Secretary Thompson and  
21 President  
22 Bush. And I very much look forward to the rest of  
23 our  
24 discussions today on obesity. Thank you all again.

25 (Applause.)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com



1 CHAIRMAN CRAWFORD: And now it's my  
2 pleasure to introduce -- we spent about a half-hour  
3 introducing you earlier, Dr. Beato. So we're not  
4 going to go into that again. Dr. Cristina Beato,  
5 please come forward.

6 DR. BEATO: Good morning. And I  
7 apologize  
8 for being late. The traffic is kind of jammed out  
9 there.

10 Thank you for the previous  
11 introduction.

12 I want to thank the FDA's Obesity Working Group for  
13 hosting this meeting, specifically Dr. McClellan,  
14 Dr.  
15 Crawford, and the staff at FDA who is making this  
16 possible. It's a very innovative and creative  
17 meeting.

18 And we hope that you can give feedback  
19 to  
20 Dr. McClellan and his group in how we can improve  
21 the  
22 message of really treating the obesity problem in  
23 our  
24 nation. The commitment that they have shown is  
25 truly

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrsgross.com

1 exceptional.

2 As you know, Secretary Tommy Thompson's  
3 goal for us at Health and Human Services is to do  
4 everything possible to ensure that Americans are  
5 strong, healthy, and independent.

6 The secretary has been a leader in the  
7 movement to put prevention first. No other  
8 secretary  
9 or president have ever done this to the degree and  
10 commitment that this secretary and this  
11 administration  
12 have shown. He's a tremendous advocate for the  
13 science being conducted by the best minds in the  
14 world, researchers here both at NIH and at FDA.

15 This research funded and supported by  
16 the  
17 American people has brought us wonderful treatment  
18 and  
19 cures for many diseases and chronic conditions, but  
20 we  
21 must do more to prevent them.

22 These diseases are happening at rates  
23 that  
24 we have never seen before. Seven out of ten of our  
25 fellow Americans die each year of a chronic

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 disease.

2 Most of these are preventable by simple steps:  
3 healthy eating, physical activity, and not smoking.

4 Tobacco use is still in our nation the  
5 most preventable cause of death and disease,  
6 causing  
7 440,000 deaths estimated each year and resulting in  
8 over an annual cost of more than \$75 billion,  
9 strictly  
10 in direct medical costs. After tobacco,  
11 obesity-related illnesses are one of the leading  
12 killers of Americans. Today obesity-related  
13 diseases  
14 are the fastest growing cause of death in our  
15 nation,  
16 something a decade ago you would have never thought  
17 of.

18 There are more than 300,000 Americans  
19 alone that will die this year from obesity-related  
20 heart disease, diabetes, and other illnesses  
21 directly  
22 having been affected by overweight and obesity. In  
23 the year 2000, the total annual cost of obesity in  
24 the  
25 United States was \$117 billion. That includes

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 direct  
2 medical care costs.

3 Secretary Thompson has often said that  
4 95  
5 percent of our estimated 2000 \$1.4 trillion in  
6 medical  
7 care, in health care went to direct medical care  
8 treatment with less than 5 percent being allocated  
9 to  
10 preventing disease and promoting health. That  
11 makes  
12 very little sense, folks.

13 The good news is that obesity and its  
14 co-morbidities are preventable through healthy  
15 eating,  
16 nutritious food in proper amounts. And we can't  
17 forget the other side of the coin: physical  
18 activity.

19 The bad news is that Americans are not  
20 taking the steps to prevent obesity and its  
21 co-morbidities. We need to give Americans the  
22 proper  
23 tools to make the right personal choices to better  
24 their lives.

25 We need a paradigm shift in the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 approach  
2 we have to health and health care. There is no  
3 greater imperative in American health care that  
4 switching from a treatment-related society to a  
5 prevention-oriented society.

6           Let's take, for example, what is  
7 happening  
8 in childhood obesity. If we stand around and do  
9 nothing, currently 15 percent of our children and  
10 teenagers are already overweight. Excess weight  
11 significantly increases our children's risk factors  
12 for a range of health problems, including diabetes,  
13 heart disease, asthma, emotional and mental health  
14 problems.

15           Fifteen years ago, many physicians  
16 would  
17 have never believed that you could say in childhood  
18 Type II diabetes. I dare to say that six percent  
19 of  
20 cases of Type II diabetes diagnosed in our nation  
21 last  
22 year were children. Unless we do something now,  
23 millions of our children will grow up to be  
24 overweight  
25 adults.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1           As a mother and as a physician, that is  
2 not acceptable. I refuse to stand by and see that  
3 happen. We must and can take simple and important  
4 steps to reduce obesity, increase physical  
5 activity,  
6 but it has to be done in a collaborative fashion.

7           This administration, President Bush,  
8 has  
9 put forth a prevention agenda focused on a  
10 healthier  
11 U.S. Healthier U.S. promotes four fundamentals of  
12 good health: physical activity, healthy eating,  
13 regular preventive checkups, and avoiding risky  
14 behavior.

15           Secretary Thompson has made this his  
16 primary prevention agenda through a program he's  
17 illustrated, Steps to a Healthier U.S. Through  
18 Steps,  
19 our department and our secretary are working to  
20 support the President's commitment throughout  
21 communities, where action will happen.

22           In keeping with Secretary Thompson's  
23 high  
24 goals for all of us at the department, Steps to a  
25 Healthier U.S. aims for nothing less than Americans

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 living longer, better, and healthier lives, as they  
2 deserve with the trust that they have put in us.

3 Steps emphasizes innovative community  
4 activities and cooperation among policy-makers,  
5 local  
6 health agencies, and the public to invest in  
7 disease  
8 prevention. In September, the secretary announced  
9 12-step grants totalling more than \$13.7 million  
10 strictly to promote community initiatives to  
11 promote  
12 better health and prevent disease. Twenty-three  
13 communities, including one tribal consortium, 50  
14 small  
15 cities in rural areas, and 7 large cities were the  
16 recipients of this.

17 One of the programs that I want to  
18 share  
19 with you, understanding the diversity of our nation  
20 and cultural sensitivities, is one managed by the  
21 Intertribal Council of Michigan.

22 Working within a community that has the  
23 second highest rate for diabetes in our nation,  
24 this  
25 program is tapping into the resurgence of interest

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 in  
2 passing on cultural, traditional wisdom and  
3 practice,  
4 including the population's history and knowledge of  
5 nutritious traditional foods, such as fish,  
6 berries,  
7 and wild rice.

8 This is just one example of a wide  
9 range  
10 of innovative steps projects that communities  
11 across  
12 our country, when called and challenged, have risen  
13 up  
14 to. I encourage you to learn more about them by  
15 visiting the Steps Web site.

16 In closing, I am going to add that the  
17 secretary and I appreciate all of you being here  
18 today  
19 and Drs. McClellan and Crawford and FDA for hosting  
20 this. This is truly a right step in the right  
21 direction.

22 We appreciate most of all the  
23 dedication  
24 that you bring to this effort of fighting this  
25 public

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com



1 health really epidemic in our nation today called  
2 obesity.

3           You're in great company. Our  
4 administration is committed to community-based,  
5 evidence-based, scientifically sound public health  
6 policies and initiatives to ensure that our  
7 Americans'  
8 health and well-being exist for today and, most  
9 important, for the future.

10           Those of you here today are health  
11 professionals, researchers, policy-makers, perhaps  
12 some advocates. You are also parents, and you are  
13 role models in your communities.

14           I charge you to make healthy personal  
15 choices in your own lives so you can be an example  
16 and  
17 a role model for the children around you. I ask  
18 you  
19 to work with us to support our efforts to put  
20 prevention first, to win our nation's obesity  
21 epidemic  
22 before it has a chance to reach another generation  
23 of  
24 Americans.

25           Thank you, and God bless you.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 (Applause.)

2 DR. BEATO: Keep up the work.

3 CHAIRMAN CRAWFORD: Cristina, thank you  
4 very much for those remarks and also for all you  
5 have  
6 done to correct health disparities and the other  
7 chronic disease and public health problems that we  
8 are  
9 experiencing today in our country. Your  
10 contributions  
11 are very much appreciated. We also want you to  
12 keep  
13 up the good work.

14 As a preliminary to our discussion of  
15 the  
16 FDA Obesity Working Group and its charge, I would  
17 like  
18 to highlight several key points about this meeting  
19 and  
20 opportunities for becoming actively involved in our  
21 work.

22 First, this meeting is being Webcast  
23 and  
24 will be archived for future viewing on the Web page  
25 for this meeting. Pertinent information about this

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 Web page is included in your packets. I hope that  
2 you  
3 will let your colleagues know about this  
4 opportunity  
5 to learn more about today's proceedings if they  
6 were  
7 unable to attend.

8 We are taking public comments on the  
9 six  
10 discussion questions that Commissioner McClellan  
11 mentioned. We are asking that you submit your  
12 comments to us by November 21 of this year. We  
13 have  
14 a place in the registration area where you can  
15 submit  
16 comments at this meeting. And they will be  
17 included  
18 in the docket.

19 Third, we will have a transcript of  
20 today's proceedings available on the Web page for  
21 this  
22 meeting in about 15 days. Once the transcript is  
23 posted on the Web page, we will notify you. We  
24 will  
25 ask your help in letting your colleagues know about

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 this resource.

2 Fourth, following this session, we will  
3 begin the public participation session of the  
4 meeting.

5 This is scheduled to begin after a lunch break at  
6 11:30. If we are able to finish earlier than  
7 anticipated, however, we will start the public  
8 participation session before lunch.

9 Fifth, the schedule of presentations is  
10 provided in your packets.

11 Sixth, we are very interested in  
12 learning  
13 about your views on the six discussion questions.  
14 This includes everyone here and everyone that this  
15 conference will be brought to their attention.

16 To the degree that time permits, we  
17 will  
18 try to have an open discussion session for each  
19 question. We will also seek other modalities and  
20 would appreciate your advice in this area to bring  
21 this to as much of the American public as we  
22 possibly  
23 can.

24 Finally, if you have any questions  
25 about

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 the meeting and where you can find things here at  
2 the  
3 Masur Auditorium, please ask our meeting staff.  
4 And  
5 they will help you.

6 INTRODUCTION OF FDA PANEL

7 CHAIRMAN CRAWFORD: Before we begin the  
8 presentation of the FDA Obesity Working Group and  
9 our  
10 key activities, I would like to introduce you to  
11 the  
12 working group members, who are the panel and are  
13 officiating at today's proceedings. I would ask  
14 them  
15 to come forward and take their place. You should  
16 sit  
17 right behind your name card, Mr. Levitt.

18 First, Joe Levitt, Director of FDA's  
19 Center for Food Safety and Applied Nutrition and  
20 Vice  
21 Chair of the Obesity Working Group. Next, Dr. Alan  
22 Rulis, who is Senior Advisor for Applied Nutrition  
23 with FDA's Center for Food Safety and Applied  
24 Nutrition. Alan?

25 Next, Mike Landa, who is Deputy Chief

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

1 Counsel of FDA. Mr. Peter Pitts is Associate  
2 Commissioner for External Relations. Dr. David  
3 Orloff  
4 is Director of the Division of Metabolic and  
5 Endocrine  
6 Drugs with the FDA's Center for Drug Evaluation and  
7 Research.

8 OVERVIEW OF THE FDA OBESITY WORKING GROUP

9 OPENING REMARKS

10 CHAIRMAN CRAWFORD: As a preface to Dr.  
11 Rulis' presentation, I would like to provide a  
12 brief  
13 background on the FDA Obesity Working Group.

14 This past August, FDA Commissioner  
15 McClellan formed an Obesity Working Group charged  
16 with  
17 developing by mid February of 2004 a plan for  
18 reaching  
19 the following goals.

20 It made the mistake of asking the  
21 commissioner what he meant by "mid February"  
22 because  
23 Mr. Levitt and I had been on a previous task force  
24 that he caused to be formed. He said mid February  
25 was

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 February 12th. That is known around FDA as  
2 McClellan  
3 math. But we will have a report by February 12th.

4 We are to design a clear, coherent, and  
5 effective FDA message that will unify public and  
6 private efforts to reverse the obesity epidemic.  
7 We  
8 are to outline an education campaign on the hazards  
9 of  
10 obesity and their prevention.

11 We are to support the message by  
12 developing an approach for enhancing and improving  
13 the  
14 food label to assist consumers with healthy dietary  
15 choices. We are to find a way of working with the  
16 restaurant industry to create an environment  
17 conducive to better informed consumers.

18 We are designing an approach for  
19 facilitating the development of medical products  
20 for  
21 the treatment of obesity. We are identifying  
22 applied  
23 and basic research relative to obesity, including  
24 the  
25 development of healthier foods and better

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 understanding of consumer behavior and motivation.  
2 And we are providing a dialogue with interested and  
3 concerned organizations and individuals on how to  
4 make  
5 this scheme work.

6 Dr. McClellan requested that I chair  
7 the  
8 FDA Obesity Working Group, but I would especially  
9 like  
10 to recognize Joe Levitt, who serves as the vice  
11 chair  
12 of the working group. Joe's contributions to this  
13 effort will be invaluable. And I am delighted to  
14 have  
15 him join me in leading this initiative.

16 I will also ask that the members of the  
17 working group who are here with us today stand so  
18 that  
19 our audience can see who you are. And they are  
20 sitting now, and you can see who they are. So at  
21 ease.

22 Dr. Rulis and his team will now provide  
23 more detailed information about the working group,  
24 its  
25 organization and work. He will also provide you

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com



1 with  
2 more details about a significant project the  
3 working  
4 group is undertaking to establish a knowledge base  
5 on  
6 public and private sector initiatives addressing  
7 obesity.

8 Before we conclude this session, Joe  
9 will  
10 summarize the key points.

11 MEMBER RULIS: Thank you, Dr. Crawford.

12 OVERVIEW

13 MEMBER RULIS: I would ask my  
14 colleagues  
15 Dr. Donna Howard and Rick Canady to come forward  
16 and  
17 occupy the chairs in the front. The three of us  
18 will  
19 give a series of presentations which will hopefully  
20 inform you a little bit more about the working  
21 group  
22 and how it's structured and what it intends to try  
23 to  
24 accomplish between its original charge in August of  
25 this year and February next year.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   For the record, I am Alan Rulis, the  
2 Senior Advisor for Applied Nutrition in the Center  
3 for  
4 Food Safety and Applied Nutrition at FDA. And I am  
5 serving in this role to coordinate a lot of the  
6 work  
7 that is being done by this Obesity Working Group.

8                   I would like to take you through a few  
9 slides that will give you an idea of how this group  
10 is  
11 organized and what it is going to try to do between  
12 the initial charge of August and February, mid  
13 February, of next year.

14                   The charge to the working group was  
15 delivered in a letter to Deputy Commissioner  
16 Crawford  
17 and Center Director Joe Levitt on August 1st, 2003.  
18 And the request was to provide an action plan to  
19 the  
20 commissioner by February of 2004.

21                   The members are listed on the next  
22 several  
23 slides. And I think just for the record, we will  
24 put  
25 them all up here. I will take you down through the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 list quickly. You can see that we have Pat Kuntze,  
2 Senior Advisor of Consumer Affairs, on the agenda.

3 We

4 have Pete Salisbury, Acting Director of the  
5 executive

6 operations staff; myself; Susan Bond, Special

7 Assistant to the Deputy Commissioner. We have Dr.

8 Donna Howard, my special assistant; Dr. Christine

9 Taylor, Director of the Office of Nutritional

10 Products, Labeling, and Dietary Supplements in

11 CFSAN;

12 Dr. Elizabeth Yetley, a lead scientist for  
13 nutrition

14 in the Center for Food Safety and Applied  
15 Nutrition;

16 Dr. Kathy Ellwood, the Director of the Division of

17 Nutritional Programs and Labeling in CFSAN; Dr.

18 David

19 Acheson, who is the Chief Medical Officer in CFSAN;

20 Richard Williams, Dr. Richard Williams, Director of

21 our Division of Market Studies; Dr. David Orloff,

22 Director of the Division of Metabolic and

23 Endocrinologic Drugs in our Center for Drug

24 Evaluation

25 and Research; Dr. Jonca Bull, also from CDER; Mr.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 Peter Pitts, Associate Commissioner for External  
2 Relations in the Office of the Commissioner; Mike  
3 Landa, the Deputy General Counsel, Office of Chief  
4 Counsel; Tomas Philipson, the Senior Economic  
5 Advisor  
6 to the Commissioner; Serina Vandegrift, the Senior  
7 Advisor for Policy and Operations to the  
8 Commissioner;  
9 and Mary-Lacey Reuther, a Special Assistant to the  
10 Commissioner.

11 We have a number of adjunct members  
12 from  
13 around the agency who are also assisting in the  
14 work  
15 of the working group: Dr. Virginia Wilkening, the  
16 Deputy Director of our Office of Nutritional  
17 Products,  
18 Labeling, and Dietary Supplements in CFSAN; Dr.  
19 Steven  
20 Bradbard, supervisory psychologist in the Division  
21 of  
22 Market Studies in CFSAN; Dr. Lisa Lubin, a consumer  
23 safety officer in CFSAN; Dr. Rick Canady, a senior  
24 science policy analyst, also on stage here, from  
25 the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 Office of the Commissioner; Jeff Shuren, Assistant  
2 Commissioner for Policy; Susan Bernard, a policy  
3 analyst in the Office of the Commissioner; Susan  
4 Wood,  
5 the Director of the Office of Women's Health in the  
6 Office of the Commissioner; and Dr. Joanne Lupton,  
7 a  
8 visiting scholar from Texas A&M University, who is  
9 with us for about a year in CFSAN.

10 The charge, as Dr. Crawford explained  
11 momentarily ago, to this working group is to  
12 provide  
13 to the commissioner in February an action plan in  
14 some  
15 detail that lays out a clear and effective message  
16 on  
17 obesity and how the FDA can communicate the  
18 importance  
19 of controlling this epidemic in the United States.

20 To undergird that message, we are to  
21 outline an education program that can help deliver  
22 that message and then to support that message with  
23 several initiatives: one, focusing on the food  
24 label,  
25 which is a primary area of FDA authority, look at

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrgross.com

1 the  
2 role of restaurants since so large a number of our  
3 citizens eat a large portion of their daily food in  
4 the restaurant setting, to focus on therapeutic  
5 treatments. That would include both drugs and  
6 medical  
7 interventions of various types and also to focus on  
8 research needs, where does the research need to be  
9 done in order to support our efforts against  
10 obesity.

11 We need also to take into consideration  
12 stakeholders in order to ensure that we are  
13 listening  
14 to what people are saying and also to make our  
15 message  
16 and our programs more effective.

17 in order to accomplish the work of  
18 this  
19 working group, we have divided up into a series of  
20 subgroups. I think it's of some value to the  
21 audience  
22 here to get an idea of what these subgroups are  
23 about.

24 The first one is the so-called  
25 Knowledge

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 Base Subgroup. And it's an important part of our  
2 work  
3 because their job is to get their arms around all  
4 of  
5 the existing work that is currently being done in  
6 this  
7 area by government agencies and academia, in the  
8 private sector, in the consumer advocacy area, and  
9 to  
10 try to understand what has already been done, what  
11 is  
12 currently being done, and what is planned so that  
13 we  
14 can orient our work in a complementary way and in  
15 an  
16 effective way that makes best use of FDA's  
17 particular  
18 unique resources.

19 That is why we have set aside time this  
20 morning after I speak for Dr. Howard and Dr. Canady  
21 to  
22 talk a little bit more about the work of that  
23 Knowledge Base Working Group so that you can get a  
24 picture of what they found out and, for the record,  
25 to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrsgross.com

1 document what we now know of to be the spectrum of  
2 things that are going on in the obesity area.

3 We also have a Message Subgroup that  
4 will  
5 talk about the development of the message. I will  
6 go  
7 in some detail on all of these in a moment; the  
8 subgroup that is focused on getting this public  
9 meeting together, which is a very important part,  
10 we  
11 think, of our effort; the subgroup focused on the  
12 food  
13 label; one on restaurants and industry; one on the  
14 education program we would like to try to develop;  
15 and  
16 then, of course, therapeutic treatment, research,  
17 and  
18 eventually writing our report for the commissioner.

19 I've talked a little bit about the  
20 Knowledge Base Subgroup. You will hear much more  
21 in  
22 a moment from my two colleagues up here. Let's  
23 talk  
24 a little bit about the Message Subgroup. Their  
25 goal

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com



1 will be to identify existing messages in the public  
2 and private sector, to review these messages for  
3 appropriateness and effectiveness, and then to  
4 present  
5 options for consideration of the full Obesity  
6 Working  
7 Group. This will then become a part of our report  
8 to  
9 the commissioner.

10 Our Public Meeting Subgroup, I would  
11 like  
12 to take this opportunity to thank Pat Kuntze in the  
13 Office of the Commissioner for her work in helping  
14 to  
15 get this up and all of her colleagues. This public  
16 meeting is one very important part of our effort to  
17 try to make this working group effective.

18 What we really want to do is receive  
19 input. The key words here are "receive input" from  
20 all of the people that are working on the subgroups  
21 in  
22 our working group and also the people in this  
23 audience  
24 that are assembled. We are very anxious to receive  
25 your ideas, your thoughts in response to our six

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 questions.

2           The Labeling Subgroup is intending to  
3 examine the statutory framework for labeling with  
4 respect to reducing obesity and preventing weight  
5 gain. They will also be looking at the outcome of  
6 a  
7 meeting that we have planned for November 20th.  
8 You'll hear a little bit more about that  
9 momentarily  
10 as well.

11           In conjunction with the Department of  
12 Health and Human Services, we are conducting a  
13 workshop, again to take place at NIH, at the Lister  
14 Hill Auditorium, on November 20th and to focus on  
15 the  
16 relationship between food packaging and food  
17 labeling  
18 and individuals' attempts to control their weight.  
19 And, of course, we will have recommendations from  
20 that  
21 Labeling Subgroup that will then be incorporated in  
22 our final report.

23           A Restaurant Industry Subgroup will  
24 look  
25 at essentially the restaurant industry and trade

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 associations and pursue dialogue with them to try  
2 to  
3 exchange information, understand the situation in  
4 that  
5 regard, and provide input to the Obesity Knowledge  
6 Group and also the working group at large to  
7 develop  
8 recommendations on approaches to encourage the  
9 restaurant industry to take appropriate steps to  
10 address the obesity epidemic. We also would like  
11 to  
12 make sure that we have good representation from  
13 that  
14 sector in our November 20th workshop at NIH here.

15 Education Program Subgroup is focused  
16 on  
17 exploring and developing answers to the following  
18 questions, what are the target populations for an  
19 education program, what are the most effective  
20 modes  
21 for delivering that program, how do we know the  
22 messages will be received, and how would we  
23 evaluate  
24 whether the education programs or messages will be  
25 effective.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1                   We would intend to work with DHHS  
2 counterparts to determine how FDA's obesity  
3 outreach  
4 and education efforts fit into the larger context  
5 of  
6 DHHS' efforts to control obesity and also to  
7 provide  
8 recommendations to the full working group as part  
9 of  
10 our report.

11                   The Therapeutic Treatment Subgroup is  
12 intending to gather information on existing  
13 therapeutics for obesity treatment. And that would  
14 include drugs, devices, and other medical  
15 interventions and to really look at what barriers  
16 there might be to the development of newer enhanced  
17 therapeutics and also to make their  
18 recommendations.

19                   A Research Subgroup will be identifying  
20 existing research as well as research gaps in  
21 obesity.

22 And those would be including, but not limited to,  
23 the  
24 development of healthier foods and better  
25 understanding of consumer behavior and motivation

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 so  
2 we have both what we would call bench research,  
3 hard  
4 science research, as well as sociological research  
5 in  
6 human behavior. They will also present their  
7 recommendations.

8                   The Report Writing Group is charged  
9 with  
10 producing a report for the commissioner in  
11 February,  
12 which we fully intend to do. And we expect that  
13 the  
14 outcome of this meeting, the transcript and the  
15 comments and suggestions we receive during this  
16 meeting will greatly enhance our ability to produce  
17 a  
18 cogent, a coherent, and comprehensive report for  
19 the  
20 commissioner.

21                   So, with that, I will turn to my  
22 colleagues on the podium up here. Dr. Donna Howard  
23 with the Center for Food Safety and Applied  
24 Nutrition  
25 will start. And she will be followed by Dr.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 Richard

2 Canady.

3 They will both be discussing the work  
4 of  
5 our Knowledge Base Group and what they have  
6 discovered  
7 so far in their work.

8 BUILDING A KNOWLEDGE BASE ABOUT OBESITY

9 DR. HOWARD: Good morning. Dr. Rick  
10 Canady, Ms. Corrina Sorenson, and I have prepared  
11 the  
12 following presentation, very briefly outlining some  
13 of  
14 the past and current projects related to overweight  
15 and obesity and nutrition.

16 The activity of researching and  
17 cataloguing this information on the past and  
18 current  
19 efforts in this area is an important one. It is  
20 important for us to perform because by knowing what  
21 else is out there, we can best decide what we as an  
22 agency can offer and how it will fit within and  
23 complement what others are doing, as Dr. Rulis  
24 pointed  
25 out.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 I want to stress before I get started  
2 that  
3 this presentation is simply intended as an overview  
4 and a set of examples of activities. Not every  
5 effort  
6 or project will be addressed, nor can they all be  
7 since there is so much current activity in the area  
8 of  
9 overweight and obesity.

10 To start out with, some examples of  
11 academic research include some work at Stanford's  
12 Prevention Research Center, which is doing  
13 extensive  
14 work related to the modification of social and  
15 personal factors known to implement a series of  
16 chronic diseases, including obesity.

17 Tufts School of Nutrition Science and  
18 Policy is involved in a series of activities and  
19 programs related to the dissemination of  
20 information  
21 related to overweight and obesity, including the  
22 National Theatre for Children, which presents an  
23 interactive nutrition and fitness performance play  
24 for  
25 elementary school children entitled "The Prince and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 the Pyramid."

2 And the University of Pennsylvania is  
3 conducting quite a bit of research related to  
4 nutrition and the prevention of obesity, including  
5 a  
6 number of efforts in conjunction with research  
7 foundations.

8 A lot of industry efforts related to  
9 obesity involve work being done on drugs and  
10 devices  
11 to treat obesity. Dr. Canady will talk about that  
12 area during his portion of the presentation, but I  
13 wanted at this point to focus on activities  
14 involving  
15 the prevention of overweight and obesity and work  
16 that  
17 the food industry is doing towards this goal.

18 Kraft's obesity initiative is a good  
19 example of that. Kraft's Worldwide Health and  
20 Wellness Advisory Council is working to help Kraft  
21 structure its ongoing response to obesity and to  
22 address other health and wellness issues and  
23 opportunities.

24 Kraft's obesity initiative includes  
25 limiting portion sizes consumed by Americans. And

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com



1 one  
2 of the ways that they intend to do this is by  
3 marketing their products in single serving  
4 packages.

5 Kraft will also be developing nutrition  
6 guidelines for all of their products, both existing  
7 and new. The guidelines will include levels for  
8 calories, total fat, saturated fat, trans fat,  
9 cholesterol, sugars, and sodium.

10 Finally, Kraft recognizes the concern  
11 surrounding the marketing of food in schools. And,  
12 as  
13 a result, they decided to discontinue this  
14 practice.

15 Kraft does stress, however, that this move will not  
16 affect any future charitable contributions that  
17 they  
18 will make to schools.

19 For restaurants, I've chosen here two  
20 quick-serve chains, Wendy's and McDonald's, again  
21 just  
22 as examples of work being done. The quick-serve  
23 chains seem to be more aggressively addressing the  
24 issue of overweight and obesity. This is probably  
25 because they have been targets of the obesity

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 litigation against restaurants to date.

2 I'll start with Wendy's. They've begun  
3 providing general nutrition and fitness information  
4 on  
5 their tray liners as well as the suggestion to ask  
6 for  
7 a nutrition guide, which they have also put on all  
8 of  
9 their to-go bags.

10 Also, if you go to Wendy's Web site,  
11 there's a build a meal section, where you can place  
12 your order from the Wendy's menu and be provided  
13 with  
14 nutritional content information associated with  
15 your  
16 chosen meal.

17 McDonald's has a similar service on  
18 their  
19 Web site called "Bag a McMeal." And McDonald's has  
20 also introduced their healthy lifestyle initiative,  
21 which includes menu choice, physical activity, and  
22 education.

23 To address menu choice, McDonald's is  
24 introducing the salads and more menu to the  
25 marketplace and will unveil new items with less

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4122

www.nealr.com

1 than  
2 ten grams of fat as healthier options to help  
3 communicate the message of a healthier lifestyle.

4 McDonald's also recognizes that  
5 physical  
6 activity is an important component to a healthier  
7 lifestyle. And so they have enlisted the help of  
8 best-selling author, professional exercise  
9 physiologist, and Oprah Winfrey's personal trainer,  
10 Bob Green, to help them develop educational  
11 materials,  
12 including booklets and tray liners. And he will  
13 also  
14 be conducting speaking engagements on McDonald's  
15 behalf.

16 Some research foundations have also  
17 weighed in on the obesity issue. IFIC has a  
18 section  
19 on their Web site called New Nutrition Conversation  
20 With Consumers," where consumers can get  
21 information  
22 on dietary fats and sweet foods and beverages and a  
23 variety of other foods as well as a list of eating  
24 tips. Also on this Web site, IFIC stresses the  
25 importance of physical activity in managing weight.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrgross.com

1 IFIC also sponsors a Web site called  
2 Kidnetic, which is geared toward teaching children  
3 about good nutrition and physical activity in  
4 weight  
5 management.

6 ILSI's PAN Program is being conducted  
7 in  
8 collaboration with the University of Pennsylvania's  
9 Weight and Eating Disorders Program. And it's  
10 designed to evaluate possible predictors of  
11 overweight  
12 and obesity at various points during the first  
13 years  
14 of life. ILSI's Take Ten Project is also geared  
15 toward children and, according to their slogan,  
16 getting kids active ten minutes at a time.

17 Industry and restaurant trade  
18 associations  
19 have also provided their take on the obesity and  
20 overweight issue. This slide lists the GMA's  
21 advice  
22 to the USDA regarding their update of the dietary  
23 guidelines.

24 Their advice includes some physical  
25 activity in the connection between calories

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 consumed  
2 and calories burned. They address educating the  
3 public with regards to standard serving sizes. And  
4 they suggest that the USDA incorporate physical  
5 activity and nutrition education into America's  
6 schools.

7 This quote from the National Restaurant  
8 Association press release entitled "Fitness is Key  
9 to  
10 Healthy Lifestyle" outlines the National Restaurant  
11 Association's position on the role of food in the  
12 obesity issue.

13 And now on to a consumer group. CSPI  
14 has  
15 historically been raising issues concerning  
16 unhealthy  
17 foods, what they consider to be unhealthy foods,  
18 movie  
19 theatre popcorn, Chinese food, trans fat, as well  
20 as  
21 a number of other things.

22 Among other things you find on their  
23 Web  
24 site are suggestions to improve your diet and  
25 health,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 including the ten foods you should eat and the ten  
2 foods you should never eat.

3 Also on their Web site is a policy  
4 option  
5 section, where consumers can find information about  
6 what CSPI thinks should be done by the food  
7 industry  
8 and government agencies, like FDA, to improve the  
9 nation's nutritional status and what steps  
10 consumers  
11 can take to compel industry and government to take  
12 these actions.

13 CSPI also provides a school foods tool  
14 kit, consisting of advice to schools on how to  
15 improve  
16 the food and beverage choices that they provide to  
17 the  
18 children that go to those schools. They offer  
19 materials and policies to carry out the changes and  
20 there's a list of success stories from schools who  
21 have successfully implemented CSPI strategy.

22 The Center for Consumer Freedom has a  
23 section on their Web site concerning the activities  
24 of  
25 overweight and obesity titled "Your Foods Under

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 Attack."

2 Also in this section, there is a  
3 discussion about the consequences of some of the  
4 actions being taken by a variety of groups. One  
5 example of this is an article on the consequences  
6 of  
7 obesity-based litigations against restaurants and  
8 the  
9 food industry on a society that they feel is being  
10 taught not to take personal responsibility for the  
11 consequences of their choices and actions.

12 Another example is an article outlining  
13 the consequences to the insurance and medical  
14 systems  
15 of classifying obesity of a disease.

16 According to a recent Washington Post  
17 article, legislatures in at least 25 states are  
18 currently debating more than 140 bills aimed at  
19 curbing obesity. New state laws currently under  
20 consideration would restrict the sale of soda and  
21 candy in public schools, require fast food chains  
22 to  
23 post fat and sugar content directly on the menu  
24 boards, and even attempts to tax the fat away.

25 Here are a few example. Again, this is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 not an exhaustive list or maybe even the most  
2 up-to-date list but simply some examples of state  
3 activity in this area.

4 A California soda ban was signed into  
5 law  
6 at this end of this past September by then Governor  
7 Gray Davis. This legislation bans the sale of soda  
8 in  
9 public elementary and middle and junior high  
10 schools  
11 beginning next July.

12 City council member Phil Mendelson is  
13 working on legislation that would require city  
14 restaurants in the nation's capital to print  
15 nutritional information alongside food items on  
16 menus.

17 Just this past week, Governor Jeb Bush  
18 signed an executive order creating the Governor's  
19 task  
20 force on the obesity epidemic, which is a 14-member  
21 group that will develop strategies to tackle the  
22 Sunshine State's weight problem.

23 Finally on this slide, the nonprofit  
24 organization Commercial Alert has started a  
25 campaign

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com



1 to help stop the childhood obesity epidemic by  
2 banning  
3 the marketing, distribution, and sale of snack  
4 foods  
5 in schools.

6 And on the heels of this effort,  
7 Assemblyman Oritz was introduced a bill that would  
8 add  
9 a surcharge on video game rentals and sales, TV  
10 advertising, and corporate America's fast food  
11 industry. Oritz says that if an industry is making  
12 people obese, then it should be responsible and at  
13 least contribute to prevention.

14 Here is some proposed federal  
15 legislation  
16 listed here. Representative Ric Keller has put  
17 forward the Personal Responsibility in Food  
18 Consumption Act. And Senator Mitch McConnell has  
19 introduced the Common Sense Consumption Act. These  
20 acts are designed to prevent lawsuits against the  
21 manufacturers, distributors, or sellers of food or  
22 nonalcoholic beverage products with the exception  
23 of  
24 lawsuits, including those claiming false  
25 advertising

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 or injuries from food consumption.

2 Democratic Representative Rose DeLauro  
3 has  
4 proposed and is seeking cosponsors for the  
5 Restaurant  
6 Information Act of 2003, which would require  
7 restaurant and fast food chains to have 20 or more  
8 locations to put trans fat and saturated fat,  
9 calorie,  
10 and sodium information beside each item on a menu.

11 John Banzhaf, law professor at George  
12 Washington University and noted tobacco attorney,  
13 has  
14 been quoted as saying that there have been seven  
15 obesity lawsuits filed. I'm taking this  
16 information  
17 from an issue of Obesity Policy Report.

18 In that issue, Obesity Policy Report  
19 goes  
20 through those seven cases and comes up with  
21 actually  
22 three cases where the obesity has been blamed on a  
23 food industry or a restaurant.

24 The suits that are strictly considered  
25 obesity suits include a lawsuit against Kraft for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 not  
2 strictly putting their amount of trans fat on their  
3 Oreo cookies, on the labels for their Oreo cookies.  
4 After what the filing lawyer determined to be an  
5 appropriate amount of publicity, that suit was  
6 dropped.

7 A suit has been filed against  
8 McDonald's  
9 on behalf of Cesar Barber, a 56-year-old  
10 maintenance  
11 worker who claims that McDonald's contributed to  
12 his  
13 obesity, diabetes, and heart disease. And while  
14 this  
15 case has not been officially withdrawn, there has  
16 been  
17 little recent activity on it.

18 Probably the most well-known case of  
19 this  
20 type was filed on behalf of Ashley Pelman and  
21 Jazlyn  
22 Bradley, two New York teenagers who allege that  
23 McDonald's food contributed to their obesity.

24 This case was considered to have a  
25 little

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 bit of a better chance than the Barber case since  
2 we're talking about children here, as opposed to  
3 adults, who are more likely to be expected to be  
4 responsible for the consequences of their choices,  
5 but  
6 the case was dismissed, refiled, and recently just  
7 dismissed again with strict instructions from the  
8 judge that it not be refiled.

9 My next few slides are on what is being  
10 put out there by various forms of the media. I  
11 thought this was important to address because  
12 articles  
13 and programming on obesity and weight management  
14 seem  
15 to be pouring out of the media at a rate that could  
16 understandably be seen as overwhelming to the  
17 general  
18 public.

19 For an example, Time magazine and U.S.  
20 News and World Report have each in the past little  
21 more than a year had two cover articles on the  
22 issue  
23 of nutrition and/or overweight and obesity. And,  
24 again, these are just examples. There's plenty  
25 more

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 out there.

2 I did a quick search on Amazon Books  
3 only  
4 on the word "diet" and came up with more than  
5 31,000  
6 matches. I realize that that includes things like  
7 how  
8 to control diabetes by diet and perhaps the vegan  
9 diet. So then I went on to narrow the search to  
10 weight loss and came up with still almost 2,000  
11 matches, the top 3 of which are listed here. This  
12 is  
13 just an example to show you what is out there and  
14 what  
15 the public is being exposed to.

16 Television. I have two examples here  
17 for  
18 what people are hearing through television. The  
19 first  
20 is the Food Network has two shows currently. The  
21 first one is called Cooking Thin. Kathleen  
22 Dealemans  
23 hosts the show with real people, gets down with  
24 people  
25 and explains to them how they have time to fit

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 healthy  
2 eating and physical activity into their busy  
3 lifestyles. Kathleen herself has battled obesity.  
4 So  
5 she knows of what she speaks.

6 Another show is Lighten Up!, which has  
7 two  
8 chefs making the same dish side by side, one  
9 following  
10 a traditional recipe and the other one low-fat and  
11 low-calorie alternatives, so trying to educate the  
12 public as to how they can cook low-fat alternatives  
13 and low-calorie alternatives.

14 Another example of television  
15 addressing  
16 the overweight and obesity issue was a two-hour  
17 special with Katie Couric at 8:00 p.m. about a  
18 month  
19 ago, not too long ago. It was advertised as a look  
20 at  
21 America's obesity crisis, but it actually seemed to  
22 be  
23 more of a two-hour advertisement of Dr. Phil  
24 McGraw's  
25 new book.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrsgross.com

1 I have a whole slide here on the Weight  
2 Watchers system because it is a well-respected  
3 weight  
4 loss and management program. Every food is  
5 assigned  
6 a point value. And as the participants eat food  
7 during the day, they add the points together from  
8 the  
9 different food groups.

10 Each participant is assigned how many  
11 points they can have per day. They're allowed 35  
12 free  
13 points a week and can actually earn more through  
14 activity points. So they can splurge a little bit.  
15 It's not about constant denial. They can have a  
16 little bit of the food that they really want to  
17 have.

18 It's considered to be successful by  
19 many,  
20 mostly based on because there is a lot of support.  
21 They have meetings, where they sit and talk with  
22 other  
23 people on Weight Watchers. There is also a  
24 maintenance program. It is suggested that they go  
25 to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 meetings for at least a year after reaching their  
2 goal  
3 weight to help them maintain that weight.

4 I am now going to move on to Ms.  
5 Sorenson's portion of the presentation and discuss  
6 programs and activities within the federal  
7 government  
8 currently underway to address the issue of  
9 overweight  
10 and obesity, including agencies within the  
11 Department  
12 of Health and Human Services and the U.S.  
13 Department  
14 of Agriculture.

15 HHS' main focus in the fight against  
16 overweight and obesity is fostering disease  
17 prevention  
18 and health promotion. Steps to a Healthier U.S. is  
19 a  
20 new initiative to advance the President's healthier  
21 U.S. goal. The program identifies and promotes  
22 programs that foster healthy behaviors and  
23 prevention,  
24 including incentives to schools for physical  
25 education

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1 programs and physical activity strategies, such as  
2 motivational signs and reminders placed near  
3 elevators  
4 and escalators, encouraging people to take the  
5 stairs.

6                   Healthy People 2010 is a comprehensive  
7 set  
8 of disease prevention and health promotion  
9 objectives  
10 developed to improve the health of all Americans,  
11 where nutrition and overweight and physical  
12 activity  
13 and fitness are leading health indicators.

14                   Healthfinder is the government's  
15 premier  
16 gateway Web site, which includes links to  
17 information  
18 on obesity, nutrition, and physical activity.

19                   National Health Information Center is  
20 an  
21 internet-accessible clearinghouse with a toll-free  
22 number that provides a central health information  
23 referral service for consumers and professionals.

24                   And the National Health Information  
25 Infrastructure aims to increase information flow

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 across sectors and with the public to provide all  
2 health decision-makers with relevant, reliable, and  
3 timely information.

4 The CDC's main focus in the fight  
5 against  
6 overweight and obesity is improving lifestyle  
7 behaviors. This focus is reflected in this quote  
8 by  
9 the current CDC director.

10 Toward their goals, CDC is engaged in  
11 several initiatives to promote benefits of healthy  
12 eating and physical activity, including Trails for  
13 Health, which is a program designed to help  
14 Americans  
15 engage in physical activity by providing them more  
16 opportunities for the activity.

17 CDC's active community environment  
18 promotes walking, bicycling, and the development of  
19 accessible recreation facilities. This initiative  
20 was  
21 developed in response to data that suggests that  
22 characteristics of U.S. communities, such as  
23 proximity  
24 to facilities, stress design, and the availability  
25 of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 pedestrian and bicycle facilities, plays a  
2 significant  
3 role in promoting or discouraging physical  
4 activity.

5 CDC's personal energy plan is a 12-week  
6 self-directed work site program to promote healthy  
7 eating and moderate physical activity.

8 And the Wise Woman Program provides 40  
9 to  
10 60-year-old women with the knowledge and skills to  
11 improve lifestyle habits to prevent, delay, or  
12 control  
13 cardiovascular or other chronic diseases.

14 In Michigan recently the Wise Woman  
15 Program developed partnerships with the local  
16 League  
17 of Women Voters in the Lansing area and a sporting  
18 goods store to provide low-income women in Lansing  
19 with high-quality athletic shoes and the  
20 opportunity  
21 to become physically active.

22 Some programs that target kids and  
23 young  
24 teens include Kids Walk-to-School, which is a  
25 program

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 that strives to increase awareness of the  
2 importance  
3 of regular physical activity for children, improve  
4 pedestrian safety, and promote healthy and walkable  
5 community environments.

6 Then there is the VERB Campaign, which  
7 is  
8 geared toward children to encourage physical  
9 activity  
10 in the pre-teen group. In addition to the  
11 commercials  
12 that you see on Disney Channel and Nickelodeon, the  
13 VERB also includes an interactive Web site where  
14 kids  
15 can determine their fitness level and record their  
16 activities and their progress.

17 Also targeted toward the health and  
18 physical activities of kids is the School Health  
19 Index, which is a tool that allows schools to rate  
20 the  
21 performance of their physical activity and  
22 nutrition  
23 programs and how to decide what steps they need to  
24 take to improve them.

25 NIH has a number of established and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 ongoing activities with regard to overweight and  
2 obesity through NHLBI, NIDDK. NHLBI works to plan,  
3 conduct, foster, and support basic research,  
4 clinical  
5 studies, and educational projects related to the  
6 causes, prevention, diagnosis, and treatment of  
7 heart,  
8 blood vessel, lung, and blood diseases.

9 NIDDK conducts and supports research  
10 and  
11 development projects on a broad spectrum of  
12 metabolic  
13 diseases, digestive disorders, and nutrition, and  
14 kidney and neurologic diseases.

15 In addition to NHLBI and NIDDK and NCI,  
16 National Cancer Institute, as well, which I'll  
17 speak  
18 about in a little bit more detail, NIH also  
19 provides  
20 information via MEDLINE and supports a variety of  
21 studies on nutritional and metabolic diseases, in  
22 which they include obesity.

23 NHLBI obesity education initiative is a  
24 decade-old program that aims to reduce the  
25 prevalence

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 of obesity to reduce the risk and health outcomes  
2 associated with coronary heart disease. The  
3 program  
4 contains both a population-based and risk-based  
5 strategy.

6 Population-based strategy includes the  
7 Jump Start school education program, an obesity  
8 education Web site, and a program called Hearts in  
9 Parks, which is a community-based program designed  
10 to  
11 help park and recreation agencies encourage  
12 health-healthy lifestyles in their communities.

13 The risk-based strategy includes  
14 overweight and obesity guidelines, the first such  
15 federal guidelines for the identification,  
16 evaluation,  
17 and treatment of overweight and obesity.

18 NIDDK has programs to address the  
19 prevention and treatment of obesity to avert the  
20 onset  
21 of diabetes and other metabolic conditions,  
22 including  
23 the National Task Force on Prevention and Treatment  
24 of  
25 Obesity; the Weight Loss Information Control

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 Network;  
2 and Sisters Together Move More, Eating Better,  
3 which  
4 is a national initiative designed to encourage  
5 black  
6 women 18 and over to maintain a healthy weight.

7           The National Cancer Institute has their  
8 well-known five to Nine a Day campaign, which is  
9 designed to encourage Americans to eat five or more  
10 servings of fruits or vegetables a day. Men  
11 actually  
12 need to eat more fruits and vegetables and  
13 currently  
14 are eating less. So they have the men's Shoot for  
15 Nine campaign.

16           The National Cancer Institute is also  
17 working on mechanisms for physical activity  
18 behavior  
19 change, which is a research initiative to increase  
20 the  
21 knowledge base necessary to develop effective  
22 physical  
23 activity interventions in children, adolescents,  
24 and  
25 the elderly.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1                   Now on to USDA. Their main focus in  
2 the  
3 fight against overweight and obesity is encouraging  
4 good nutrition. They offer a variety of tools  
5 towards  
6 this goal, including the interactive Healthy Eating  
7 Index, where you can go in and select the foods  
8 that  
9 you have eaten for that day and it will come back  
10 and  
11 give you a report, a healthy eating summary based  
12 on  
13 your food choices and how they comply with the food  
14 pyramid and the current dietary guidelines.

15                   The food pyramid is currently being  
16 revamped. In the first phase of renovation of the  
17 pyramid, USDA proposed new intake patterns  
18 detailing  
19 what and how much Americans should eat. By  
20 establishing more personal goals, USDA hopes to  
21 place  
22 greater emphasis on individual calorie balance.  
23 And  
24 for the first time, target calorie levels will  
25 assume

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1 that the average person is sedentary, not active.  
2 The  
3 new pyramid is scheduled to be complete by Winter  
4 of  
5 2005.

6 In conjunction with the updating of the  
7 pyramid is the updating of the dietary guidelines  
8 for  
9 Americans. The new pyramid will include any  
10 changes  
11 made by the 2005 dietary guidelines committee.

12 USDA Team Nutrition is designed to  
13 ensure  
14 the effective implementation of Healthy Breakfasts  
15 and  
16 Lunches in School and the teen nutrition web site  
17 is  
18 geared towards schools and has sections on how to  
19 participate in teen nutrition.

20 Some other USDA projects include "Eat  
21 Smart. Play Hard," which is a campaign designed to  
22 convey behavior-focused motivational messages about  
23 healthy eating and physical activity. And the Food  
24 and Nutrition Information Center provides consumer  
25 access to informational brochures, such as Get on

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 the  
2 Grain Train and Fabulous Fruits, Versatile  
3 Vegetables.

4 USDA also has some programs targeting  
5 low-income families to protect children's health,  
6 including the Farmer's Market Nutrition Program,  
7 which  
8 is in place because it has been shown that WIC  
9 recipients have a higher prevalence of overweight  
10 and  
11 obesity; and the School Lunch and Breakfast  
12 Program,  
13 which is a federally assisted program which helps  
14 feed  
15 children from low-income families meals meeting the  
16 applicable recommendations of the dietary  
17 guidelines  
18 for Americans.

19 Dr. Canady will now give his portion of  
20 the presentation.

21 DR. CANADY: So it's getting to be that  
22 part of the morning where the first cup of coffee  
23 has  
24 worn off and maybe standing up and sitting down  
25 would

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrsgross.com

1 be a good idea right now. If you all want to  
2 exercise, you have social permission now to stand  
3 up  
4 and wake up a little bit and then sit back down.  
5 Maybe it will help out a little bit. I wish I had  
6 some coffee up here.

7 I would like to get right into it  
8 because  
9 we have got a lot to go through. Gee, after  
10 hearing  
11 Dr. Howard talk about what has been going on, both  
12 in  
13 the outside world and within the federal  
14 government,  
15 it is not hard to see there is a whole lot going  
16 on.

17 What I would like to do right now is go  
18 through some of what FDA has been doing and is  
19 currently doing in order to give you further  
20 context  
21 by which we can hear your views on the questions  
22 that  
23 have been put forth for this meeting.

24 I grouped what I am going to talk about  
25 in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrsgross.com

1 four categories, education, regulation guidance,  
2 enforcement, and research, up there on the board.  
3 And  
4 what I would like to do is go through these  
5 individual  
6 aspects.

7 Do we have a cursor to go through?  
8 Thanks. First, within education, there is a  
9 program.  
10 If you search on our Web site for "know your  
11 label,"  
12 you can most likely come to this information.

13 Know Your Label is a Web-based and  
14 video  
15 educational materials effort on how to use  
16 nutritional  
17 labels essentially in order to make more informed  
18 choices in the context of a healthy diet.

19 We have another program, called Power  
20 of  
21 Choice, that we have been doing recently with the  
22 USDA's Food and Nutrition Service. This is a  
23 series  
24 of guided activities and material to help motivate  
25 and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 empower kids to make healthy choices, again within  
2 a  
3 balanced diet. These are within real life  
4 settings.

5 The topics include things like portion control,  
6 emotional eating, and individual fitness.

7           Again within education, we have  
8 information within the food label with regard to  
9 helping you understand what is in the food in the  
10 context of making healthy choices. For example,  
11 there  
12 are standard reference serving sizes on the  
13 nutrition  
14 facts panel. This information helps facilitate  
15 counting calories, for example, while choosing  
16 nutritious foods. You can compare vitamins across  
17 different foods and have similar calorie contents  
18 and  
19 so on.

20           Similarly, we have nutrient content  
21 claims  
22 on the label. And these are based on standard  
23 criteria, such as reduced calories, light,  
24 low-calorie, and so on. Again, this helps you  
25 understand across products what relative calorie

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 contributions you might get within a given product  
2 category.

3           Similarly, within education, -- and Dr.  
4 Howard also already talked about this with regard  
5 to  
6 the food pyramid and dietary guidelines -- this is  
7 an  
8 ongoing process that, of course, FDA has a  
9 knowledge  
10 base or has expertise associated with. And it's  
11 something that, again, helps you understand the  
12 context under which we're asking you to look  
13 through  
14 questions that have been posed.

15           Within regulation and guidance, the  
16 second  
17 category of efforts that I want to focus on today,  
18 starting out with labeling and packaging, there's  
19 research and development right now involving  
20 stakeholder interaction, focus groups, and modeling  
21 that I will go into in some more detail when I go  
22 into  
23 the research that are looking at the ways that we  
24 do  
25 regulation and guidance with regard to the label

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 and  
2 looking into new approaches to labeling conducive  
3 to  
4 weight management.

5           There's, of course, the task force on  
6 consumer health information for better nutrition  
7 that  
8 Dr. McClellan referred to earlier. It's a  
9 framework  
10 essentially to enhance conveyance of scientifically  
11 accurate information to help consumers again be  
12 better  
13 informed and make more informed choices with regard  
14 to  
15 their diet.

16           Moving into weight loss drugs within  
17 our  
18 Center for Drugs, the criteria for weight loss  
19 drugs  
20 approvals are laid out here. Essentially there are  
21 two ways of looking at a five percent weight loss  
22 criterion for weight loss drugs. You can look at a  
23 mean loss in weight, five percent mean loss, as one  
24 of  
25 the criteria cross the entire group or you can look

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 at  
2 a subset of the group. And it's described here  
3 within  
4 the slide.

5 So there are two ways of using a five  
6 percent bar essentially to show efficacy with  
7 regard  
8 to weight loss drugs. The duration of the trial to  
9 show durability of effect and to assess risk is one  
10 year with open label extension through a second  
11 year.

12 Drug approvals, I am going to have  
13 actually three slides with regard to approvals.  
14 Again, this is a way of helping you understand the  
15 context through which FDA has current in the  
16 knowledge  
17 base expertise and so on in order to reflect the  
18 questions that we have asked.

19 There are two products on the market  
20 for  
21 clinic use in obesity. One is Orlistat or Xenical,  
22 and the other is Sibutramine or Meridia. These are  
23 approved for patients with BMI of greater than 27  
24 with  
25 co-morbid conditions, such as diabetes and so on,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com



1 and  
2 also approved for BMIs of greater than 30 without  
3 those co-morbid conditions.

4 There are also approvals with regard to  
5 devices within FDA. Lumping these into three broad  
6 categories, we have devices to restrict food  
7 intake.

8 These are devices that essentially narrow the  
9 gastric  
10 pouch so that you feel more satiated more quickly  
11 with  
12 a smaller amount of food. Lap-band and similar  
13 gastric pouches, restriction devices are an example  
14 of  
15 these.

16 These are other devices that are in the  
17 investigational stages that I really can't go into  
18 at  
19 this point, but the point is that there is  
20 information  
21 with regard to devices within the knowledge base  
22 within FDA that is appropriate to this effort.

23 There are also surgical devices that  
24 are  
25 associated with surgery regarding lipoplasty,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 gastroplasty, and bypass/diversion, another method  
2 for  
3 essentially reproducing the capacity of the  
4 stomach.

5           There are also monitoring and measuring  
6 devices related to body composition. This tells  
7 you  
8 how much body fat you have in relation to other  
9 parts  
10 of your body in order to help you understand where  
11 you  
12 are with regard to the BMI and adiposity and so on.

13           Turning to food, food additive  
14 approvals,  
15 this is a broad area that covers obviously a lot of  
16 different food additives. There are things like  
17 reduced or no calorie sweeteners and reduced or no  
18 calorie fat substitutes that are part of the  
19 overall  
20 set of tools that you can use in order to help you  
21 make better choices with regard to calorie intake.

22           Moving on to enforcement, the third of  
23 four areas that I am going to talk about, there is  
24 enforcement in compliance activities with regard to  
25 labeling errors; misleading claims on products;

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 and,  
2 of course, unsafe products. In these in some  
3 cases,  
4 we share authority with FTC, Federal Trade  
5 Commission.  
6 Again, what we are trying to do right now is give  
7 you  
8 highlights, give you a context under which to go  
9 through the questions we have asked you.

10 Let me move into the fourth area now.  
11 Within research at FDA, there are three areas that  
12 I  
13 want to focus on. First is essentially social  
14 science  
15 research. That has to do with communication  
16 labeling  
17 and packaging and some other areas that we will  
18 talk  
19 about in some more detail.

20 The second area is effectiveness of  
21 treatment. And there really is just a very little  
22 bit  
23 of that going on right now within FDA.

24 And the third area is describing the  
25 causal links essentially between diet and obesity,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 between obesity and co-morbidity. Obviously we  
2 have  
3 overlap with NIH on those quite a lot.

4 Starting with essentially the social  
5 science research, there is evaluation. This is a  
6 collaborative effort that we have right now going  
7 on  
8 with the Office of the Assistant Secretary for  
9 Planning and Evaluation at HHS. There are  
10 essentially  
11 four parts of this collaborative effort that I am  
12 talking about in the first bullet here.

13 There is a November 20 workshop that  
14 Dr.  
15 Rulis mentioned in the introduction to this  
16 session.

17 In case you didn't notice it on your way in, there  
18 are  
19 flyers in the front. There are little one-page  
20 blue  
21 flyers that describe this workshop.

22 This is essentially going to be a data  
23 gathering effort. We want to essentially shake the  
24 trees and find out what is going on out there in  
25 terms

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 of data with regard to a variety of efforts that  
2 are  
3 related to weight loss and obesity.

4 I would encourage you to consider going  
5 to  
6 this workshop, but I would also encourage you to go  
7 if  
8 you have data that we can help shake free from you  
9 to  
10 help us with this effort to understand what is  
11 going  
12 on out there.

13 A second effort within this research  
14 focus  
15 is focus groups to probe new labeling and massaging  
16 in  
17 a variety of environments. We're also in the  
18 process  
19 of developing third party industry interviews to  
20 identify essentially obstacles or incentives to  
21 better  
22 products out there within industry.

23 Finally, to sort of get an overall  
24 picture  
25 of the ins and outs of the obesity issue, we're

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 developing a social science model for exploring  
2 approaches to effective weight management.

3 In addition to this effort with the  
4 Office  
5 of the Assistant Secretary for Planning and  
6 Evaluation, there are, of course, other efforts  
7 within  
8 FDA's Center for Food Safety and Applied Nutrition  
9 where we are doing research within consumer use of  
10 calorie content labeling effectively in  
11 calorie-related claims.

12 The second area of the research focus  
13 that  
14 I want to point out a little bit is that we have  
15 had  
16 some efforts with regard to effectiveness of  
17 treatment  
18 and prevention. The example here is a pilot cohort  
19 of  
20 diet and proprietary weight loss products that our  
21 Office of Women's Health has completed. This was a  
22 grant process in collaboration with other agencies.  
23 It's studied the pattern of verbal weight loss  
24 products and efficacy over a period of time.

25 The third area within research that I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

1 want  
2 to focus on -- I've only got a few more slides;  
3 we're  
4 going to be done with this so we can actually  
5 really  
6 go get coffee -- is describing the causal links.  
7 Again, I mean causal links between dietary intake  
8 and  
9 development of obesity and also obesity leading to  
10 co-morbidities.

11           Examples are listed here, genetic  
12 polymorphisms of obesity in conjunction with  
13 susceptibility to breast cancer as an example. The  
14 role of exercise and weight gain has susceptibility  
15 to  
16 mutations, the effect of surgical intervention on  
17 metabolism and on biomarkers of reduced calorie  
18 intake.

19           Also, there is an effort that has been  
20 going on for some time with regard to caloric  
21 restriction. An interesting finding here, of  
22 course,  
23 is that if you reduce caloric intake, you get  
24 longevity benefits. And you also get reductions in  
25 tumors, both malignant and non. The interest here

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 is  
2 in looking at whether smaller dietary reductions  
3 would  
4 also have an effect on those outcomes.

5           Furthermore, there are more specific  
6 mechanistic information that is being garnered with  
7 regard to contribution of what is known as the  
8 methyl  
9 group, its deficiency, which is induced by obesity,  
10 and that linkage, again, to development of cancer,  
11 heart disease, and diabetes as examples.

12           There is, furthermore, interest in sort  
13 of  
14 causal events related to development of the fetus  
15 within the environment of the womb. An example we  
16 looked at recently with regard to this is  
17 nicotine's  
18 effect on obesity outcome in children.

19           Furthermore, they have looked into rat  
20 models with regard to nutritionally induced  
21 non-insulin-dependent diabetes mellitus. Again,  
22 this  
23 is a linked morbidity that, again, provides a  
24 context  
25 under which we have expertise and value within FDA.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1                   That is the end of my slides. Thanks  
2 very  
3 much.

4                   (Applause.)

5                   VICE CHAIRMAN LEVITT: Thank you to our  
6 speakers this morning, Dr. Rulis, Dr. Howard, Dr.  
7 Canady.

8                   HIGHLIGHTS AND SUMMARY

9                   VICE CHAIRMAN LEVITT: I have been  
10 asked  
11 just to give a short summary so we kind of tie up  
12 this  
13 section of the program, move on to the next one.

14                   Again, though my name is up there, I am  
15 Joe Levitt. I am Director of the Center for Food  
16 Safety and Applied Nutrition. And I am the Vice  
17 Chair  
18 of this task force along with Dr. Crawford.

19                   I think the first thing that comes to  
20 my  
21 mind from listening to all of the presentations  
22 today  
23 is, boy, we sure have a lot of work ahead of us. I  
24 think that part is clear.

25                   But I think there is some good news

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 even  
2 kind of before we start. Number one, there is  
3 broad  
4 agreement that obesity is a major public health  
5 problem. It's not good that it is a problem, but  
6 it  
7 is good that there is agreement.

8 We're involved with lots of issues.  
9 You  
10 actually begin arguing about whether there is a  
11 problem or not. I think the fact that there is  
12 broad  
13 agreement across government, across society that  
14 obesity is a major health problem in this country  
15 starts us on the right foot.

16 Second, there also is I think  
17 reasonable  
18 agreement on major parts of a solution, that we  
19 have  
20 got to address this through a combination, a  
21 sensible  
22 combination, of better food choices and more  
23 exercise.  
24 And, again, I can tell you from my experience that  
25 is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 certainly not usually the case, that even if there  
2 is  
3 agreement on the problem, there rarely is agreement  
4 on  
5 what the solution is. And I think we should not  
6 lose  
7 sight of that.

8           There also, frankly, is enormous  
9 interest  
10 and activity among all sectors of our society.  
11 Many  
12 government agencies, academia, health  
13 professionals,  
14 consumers, industry groups, everybody wants to be  
15 part  
16 of this. All right.

17           So why is this so much work? Why is  
18 this  
19 so hard? Well, it's hard because we're talking  
20 about  
21 individual behavior. It's not at all clear exactly  
22 how to get there. And for FDA, it's not  
23 necessarily  
24 precisely clear on exactly what our role needs to  
25 be

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 within the broader department, government, and  
2 society  
3 we work in.

4 So what FDA is doing here -- and we  
5 thank  
6 you for being part of it -- is trying to take a  
7 systematic approach to defining our role and being  
8 part of the solution to this major problem. As you  
9 have seen, it is important to note we are not  
10 starting  
11 from zero.

12 FDA has a lot of activities, a strong  
13 program, the food label, the drug review system,  
14 our  
15 work with all of the various stakeholders that are  
16 here, everybody that is here. We know you well.  
17 You  
18 know us well. So we have a good base to start  
19 from.

20 What we are going to try to do is do  
21 this  
22 logically. What really is the overall message we  
23 are  
24 trying to convey? How do we educate the public  
25 about

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 that message? How do we incorporate, reinforce  
2 that  
3 message through the parts that we contribute to  
4 through the food label, through working with  
5 restaurants, through therapeutics?

6 And, finally, what more research is  
7 needed  
8 because, surely, there will be and, finally, how to  
9 pull all of this together in an action plan by  
10 February, February, just a few months away,  
11 recognizing the urgency that we all feel about this  
12 issue?

13 I think there is one final point that  
14 is  
15 clear. We can't do it alone. That's why we have  
16 this  
17 public meeting. That is why your role and  
18 contribution are so terribly important.

19 First of all, your contribution today,  
20 your public comments, we hope many of you and your  
21 colleagues will go back, think about this. We'll  
22 reflect on today's meeting, submit comments to our  
23 docket.

24 We hope to see many of you at our  
25 workshop

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 on November 20th that Rick Canady mentioned and  
2 join  
3 with us because, like all major problems in our  
4 society, we could not do it alone, but we can  
5 surely  
6 do it together.

7           Again, I thank you very much for your  
8 attention during this part of the program. I think  
9 what we will do, with the Chair's permission, is to  
10 take about a five-minute break. And we will  
11 reconfigure. And, as Dr. Crawford said and we gave  
12 advance notice, we hope, to those early on the  
13 program  
14 presenters, we will start the public presentations  
15 in  
16 about another five minutes.

17           Thank you very much. Let's have a  
18 round  
19 of applause for the presenters this morning.

20           (Applause.)

21           (Whereupon, the foregoing matter went  
22 off

23           the record at 10:44 a.m. and went back  
24 on

25           the record at 10:56 a.m.)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

## 1 PUBLIC PARTICIPATION SESSION

2 CHAIRMAN CRAWFORD: We are now going to  
3 begin the public presentation part of our hearing  
4 today. The format will be described in a moment by  
5 Mr. Joe Levitt, who is going to be moderating the  
6 remainder of this session.

7 Before we go into that and while Joe is  
8 collecting his thoughts, we have the privilege of  
9 doing something that we weren't able to do because  
10 of  
11 a meeting this morning.

12 As I mentioned in my remarks, virtually  
13 all of the operating divisions in the Department of  
14 Health and Human Services are at the instigation of  
15 the Secretary, conducting their own task force  
16 work.

17 At the end of these task forces and the reports  
18 thereof, there will be an amalgamation of them and  
19 also a gleaning of the common findings.

20 There is at the present time  
21 cross-fertilization happening. You are about to  
22 hear  
23 from the head of the task force at the National  
24 Institutes of Health. And FDA has a member of his  
25 task force and vice versa. We are all working

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 together.

2 We would not want you to leave this  
3 room  
4 or even to leave this city without thinking that  
5 this  
6 government does not have its act together. Anybody  
7 who doubts that, you are going to hear from someone  
8 who will disabuse you of that notion.

9 Dr. Allen Speigel is Director of the  
10 National Institute of Diabetes and Digestive and  
11 Kidney Diseases. He is going to speak to us for a  
12 moment about what they are doing.

13 Thank you.

14 DR. SPEIGEL: Thank you very much. I  
15 appreciate the kind invitation and want to say that  
16 I  
17 am here on behalf of Dr. Elias Zerhouni, the NIH  
18 Director.

19 I think the taped comments of our  
20 Secretary Thompson -- and we had similar comments  
21 at  
22 the recent North American Association for the Study  
23 of  
24 Obesity meeting down in Fort Lauderdale a week ago  
25 --

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com



1 indicate how high a priority the obesity epidemic  
2 and  
3 its concomitant public health implications are for  
4 this department.

5           We are truly one department, as you  
6 just  
7 heard. So that both NIH, FDA, CDC, and other  
8 components are really committed to a coordinated  
9 approach and a coordinated approach not only on the  
10 part of the HHS agencies but who in the private  
11 sector, the public in general will be necessary to  
12 tackle this really complex and difficult problem.

13           Now, Dr. Zerhouni, who has been NIH  
14 Director since May of 2002, recognizing very  
15 quickly  
16 the importance of the obesity epidemic and the  
17 implications of the various morbidities brought on  
18 by  
19 obesity, for almost each of the NIH institutes  
20 created  
21 a new NIH obesity research task force and asked me  
22 as  
23 the Director of NIDDK, the lead institute at NIH  
24 for  
25 obesity research, and currently Dr. Barbara Alving,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 the Acting Director of the National Heart, Lung,  
2 and  
3 Blood Institute, to co-chair this task force.

4 We have been meeting assiduously since  
5 our  
6 creation in April of 2003 and are well along the  
7 way  
8 to crafting a strategic plan for NIH obesity  
9 research  
10 that we aim -- and I think this is a good example  
11 of  
12 coordination -- to release to the public by  
13 February  
14 1st.

15 This will be coupled with a new Web  
16 site  
17 for the task force that will really have two  
18 audiences  
19 in mind: the large investigative community, which  
20 is  
21 really the engine that drives the knowledge base  
22 that  
23 we heard about that NIH supports for obesity  
24 research;  
25 as well as the public at large and policy leaders.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   Let me just indicate that this is not  
2 something that the NIH has come to sort of lately.  
3 Clearly the NIH has been a very important component  
4 of  
5 addressing the obesity epidemic. I want to just  
6 signify just in the brief comments a few of the  
7 areas  
8 that were important areas of advances supported by  
9 NIH  
10 research and that will be key area components of  
11 the  
12 strategic plan.

13                   One is the regulation of energy  
14 balance;  
15 that is, the regulation of food intake and of  
16 energy  
17 expenditure, including physical activity. I don't  
18 think I am denigrating the obesity research  
19 community,  
20 I am just quoting George Bray, one of the pioneers  
21 of  
22 that community, when I say that this field had been  
23 a  
24 backwater for many years. It was looked on as not  
25 a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 rigorous scientific area.

2                   And, really, things changed remarkably  
3 in  
4 1994 with the discovery of the leptin gene, the  
5 first  
6 gene for a hormone that signals from fat to the  
7 brain  
8 and is directly involved in the regulation of  
9 energy  
10 balance.     And while, quite candidly, the \$20  
11 million  
12 that Angen paid for the rights to this gene have  
13 not  
14 panned out in terms of a panacea and a therapeutic  
15 for  
16 obesity, nonetheless, this discovery set off a  
17 tremendous explosion of NIH-supported research that  
18 has led to the discovery of numerous additional  
19 components, ghrelin, peptide NPY, PYY, other things  
20 that you read about in the New England Journal and  
21 elsewhere, which really represent two things:  
22 first,  
23 a much more scientifically based understanding.  
24 When  
25 we say, "Eat less and exercise more," it's a very

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 glib  
2 statement. It's very easy to say that, but we can  
3 see  
4 from the worsening of the epidemic how difficult  
5 that  
6 is to do.

7                   The reality is that is the possibility  
8 of  
9 pharmacologic targets and, of course, the key role  
10 of  
11 the FDA in the approval process in that regard.  
12 But  
13 it is the NIH that is the discovery engine that  
14 provides the pharmaceutical industry with the  
15 targets  
16 and in some cases even the target validation.

17                   Now, the other comment, another huge  
18 area,  
19 is the area of genetic susceptibility. I realize  
20 that  
21 this seems counterintuitive. The moniker that  
22 everyone hears is, "Well, our genes haven't changed  
23 over the last several decades. It's the  
24 environment  
25 that is changing. So forget about why are genes

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 important."

2 Well, I am here to tell you they are  
3 important. If you look at the NHANES, the National  
4 Health and Nutrition Examination Survey, data, it's  
5 clear that in the same environment, different  
6 populations are differentially affected by this  
7 obesogenic environment. And the rise of what are  
8 called super obese is just one reflection of that.

9 There are already examples of rare,  
10 admittedly rare, monogenic, single gene, disorders  
11 which are enough to cause early childhood severe  
12 obesity, but it is crystal clear that most obesity  
13 is  
14 a complex interaction with multiple genes, giving a  
15 susceptibility in an obesogenic environment.

16 Why is it important to discover those  
17 genes? Again, because they offer the possibility  
18 of  
19 targeted prevention and possibly pharmacologic  
20 intervention.

21 Of course, that begs the question of  
22 genetic discrimination and stigma, two things that  
23 we  
24 must assiduously work to avoid. And policy and  
25 legislation may be relevant there.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1           Let me then also point out the issue of  
2 the co-morbidities. Not all obese individuals have  
3 Type II diabetes, nonalcoholic fatty liver disease,  
4 osteoarthritis, cardiovascular disease, and many of  
5 the other things that come along with obesity. Why  
6 is  
7 that? What are the differences? How can we  
8 identify  
9 those who are at great risk?

10           Conversely, individuals, particularly  
11 Asian American individuals, have body mass index  
12 lower  
13 than what we even define as overweight, may be  
14 already  
15 quite susceptible because of visceral and central  
16 adiposity for things like Type II diabetes.

17           So there's a tremendous amount of  
18 research  
19 that needs to be done to define the underpinnings,  
20 the  
21 mechanistic basis. And I would say I recently came  
22 from a very outstanding meeting of a group called  
23 the  
24 National Dialogue on Cancer held in Kennebunkport,  
25 Maine under the auspices of former President Bush

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 and  
2 Barbara Bush.

3 The topic was cancer and obesity. Why?  
4 Because of recent prospective studies of the  
5 American  
6 Cancer Society showing that mortality from cancer  
7 is  
8 substantially increased as a function of body mass  
9 index; finally, of course, the bottom line,  
10 prevention  
11 and therapy.

12 So the NIH is really supporting and  
13 will  
14 continue to support significant new initiatives,  
15 some  
16 very much directed at the pediatric population. An  
17 initiative on prevention of obesity in the  
18 pediatric  
19 primary care setting is just one example,  
20 school-based  
21 trials and intervention.

22 And all of these importantly, are not  
23 just  
24 "community demonstration projects." They have an  
25 evaluation. They have things that we will be able

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com



1 to  
2 learn in terms of what is successful and not  
3 successful.

4 Let me just finally indicate that there  
5 are some successes. So our Type II diabetes  
6 prevention program, the DPP, unequivocally showed  
7 that  
8 an intensive lifestyle intervention was capable  
9 through weight loss of reducing dramatically the  
10 incidence of Type II diabetes in a very  
11 heterogeneous  
12 group, 45 percent minorities, at high risk for Type  
13 II  
14 diabetes.

15 Our challenge now is to translate the  
16 results of that trial across the country in a very,  
17 very cost-effective way. That will be just one of  
18 the  
19 challenges as we join with sister agencies, such as  
20 the FDA, in combatting this obesity epidemic.

21 Thank you.

22 (Applause.)

23 CHAIRMAN CRAWFORD: Thank you very  
24 much,  
25 Dr. Spiegel.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1                   Now it's my pleasure to turn the  
2 program  
3 over to Joe Levitt.

4                   VICE CHAIRMAN LEVITT: Thank you very  
5 much.

6                   VICE CHAIRMAN LEVITT: Let me just go  
7 through a little bit of the logistics for the  
8 benefit  
9 of both speakers and the audience. We will go  
10 through  
11 one speaker at a time in the order that is not in  
12 your  
13 program but on my sheet. There is an amount of  
14 time  
15 that each speaker has requested. And so we will go  
16 ahead and grant that speaker the time that they  
17 requested so they can get their full comments in.

18                   We have up here a little time clock  
19 that  
20 the speakers will see up there. It will begin with  
21 the time that you requested, we hope. If not, wave  
22 to  
23 me or something. And you will see the time go  
24 down.

25                   There is a two-minute warning light

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 that  
2 will come on when it is two minutes from the end.  
3 We  
4 will ask speakers to try within reason to keep to  
5 your  
6 time that you possibly can so that we can move  
7 through  
8 the day in order.

9 Finally, we do ask, as I'm sure this  
10 audience will, to allow each speaker to go through  
11 their presentation and save any reactions to the  
12 end.

13 It is important that every speaker be permitted to  
14 present whatever views they have and be listened to  
15 attentively and respectfully.

16 With that, I am happy to call to the  
17 podium our first speaker, Dr. Rhona Applebaum,  
18 Executive Vice President and Chief Science Officer  
19 from the National Food Processors Association.

20 DR. APPLEBAUM: Thank you, Mr. Levitt  
21 and  
22 members of the FDA obesity task force.

23 As Mr. Levitt said, my name is Rhona  
24 Applebaum, and I am with the National Food  
25 Processors

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 Association. I appreciate this opportunity to  
2 present  
3 the views of NFPA on this most serious problem.

4 An old saying goes, "For every complex  
5 issue, there is a simple answer. And it is almost  
6 always wrong." Such is clearly the case when we  
7 consider how to address the issue of obesity in  
8 America.

9 Obesity represents a multifaceted  
10 problem  
11 requiring a multi-disciplined approach. If the  
12 primary goal is to have a real effect on preventing  
13 and reducing obesity, then how can this be  
14 accomplished?

15 Let me propose several approaches that  
16 together can help us address this critical health  
17 issue. Let me forewarn you neither I nor the NFPA  
18 have the solution. If I did, if NFPA did, speaking  
19 specifically of myself, I'd be on Dr. Phil today.  
20 And  
21 I don't. It's very complex. But NFPA has outlined  
22 approaches and suggestions using the framework of  
23 the  
24 six questions posed by the task force.

25 Let me begin with question one. That

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 has  
2 to do with the evidence regarding the effectiveness  
3 of  
4 various education campaigns to reduce obesity.

5 The literature indicates that there is  
6 considerable information about public education  
7 programs but little evaluation or evidence about  
8 their  
9 effect on weight loss or maintenance, short-term or  
10 long-term.

11 It is possible, it is no doubt probable  
12 that some of these campaigns are still too new to  
13 assess their effectiveness. And they need the  
14 necessary time. We can't prejudge these new  
15 campaigns. Nevertheless, at the end of the day,  
16 the  
17 bottom line is that overweight and obesity have  
18 continued to increase in the United States.

19 NFPA believes that all stakeholders --  
20 and  
21 that's everyone in this room, whether food  
22 industry,  
23 government, educators, academia, research  
24 institutes,  
25 consumers, or consumer groups -- need to refocus

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 their  
2 efforts on helping Americans better understand the  
3 role of diet and physical activity in attaining as  
4 well as maintaining healthy weight.

5 To this end, with focus on the diet, an  
6 excellent tool, one of the tools to assist  
7 consumers  
8 to better understand how to choose sensibly, as  
9 stated  
10 in the dietary guidelines for Americans, is the  
11 food  
12 label.

13 The food label can and should be used  
14 to  
15 create healthful diets. The nutrition facts panel  
16 also can be used as a weight management tool. The  
17 calories count message needs to be re-energized and  
18 promoted.

19 The nutrition facts panel was developed  
20 and designed to help make consumers aware of the  
21 various nutritional components in foods. And we  
22 continue to support this purpose. However, the  
23 architecture, the format, and layout of the  
24 nutrition  
25 facts panel for the past decade have been focused

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 more  
2 on dietary fat and information related to heart  
3 disease risk reduction than on calories or overall  
4 diet.

5           It is our opinion that FDA should  
6 reexamine the nutrition label, daily values, and  
7 associated issues. We recommend that all  
8 statements  
9 of the food and health community should place more  
10 emphasis on educating the consumer in using the  
11 food  
12 label to identify information about the energy for  
13 weight maintenance and obesity prevention.

14           Education was part of NLEA, but it  
15 needs  
16 to be revived with commitment and investment from  
17 three departments: HHS; USDA; and, yes, the  
18 Department of Education. For example, FDA should  
19 encourage reviewing successful education programs,  
20 such as the National Cholesterol Education Program,  
21 NCEP, and how a similar model could be used for  
22 obesity.

23           Perhaps if people know their numbers in  
24 terms of healthy weight goals, easy numbers,  
25 healthy

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 weight, or weight target, and physical activity  
2 needs,  
3 that and other measurements, the way most Americans  
4 know their cholesterol target and value, we can  
5 slow,  
6 if not curb, the rise in overweight and obesity or  
7 help to slow this increase, a change in the  
8 prevalence  
9 arrow from pointing up to pointing down.

10           NFPA also encourages FDA to support the  
11 components of the Healthier U.S. initiative with  
12 two  
13 of the four central components focusing on physical  
14 activity and healthy food choices. These points  
15 were  
16 already raised by the commissioner.

17           Regarding question two, FDA also asked  
18 for  
19 views related to any specific priorities for  
20 children.

21 NFPA believes that development of lifelong eating  
22 habits and physical activity patterns begin early  
23 and  
24 are fostered via parental example and  
25 responsibility.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1 Once children enter school, the school environment  
2 is  
3 also key. Again, education is essential.

4 As for the role of the Department of  
5 Education, a solid understanding of the basics of  
6 sound nutrition, the importance and fun of physical  
7 activity, and the components of a healthy lifestyle  
8 must be part and parcel of our nation's educational  
9 curriculum. And we must start early.

10 We must give children a solid healthy  
11 start on the road to sound nutrition practices and  
12 physical activity programs and provide them with  
13 the  
14 environment and opportunities to put these  
15 practices  
16 and programs into action.

17 Today's children should be as  
18 well-versed  
19 in what constitutes sound nutrition and physical  
20 activity practices as they are with environmental  
21 principles. In my own household, that has to do  
22 with  
23 trash sorting and recycling.

24 All three departments have a role to  
25 play

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 in fostering and supporting coordination among  
2 government agencies at the federal, state, and  
3 local  
4 levels to improve messages in its education  
5 programs  
6 for children.

7           Additionally, up-to-date data on food  
8 consumption and health status variables, including  
9 physical activity, are needed for children and  
10 across  
11 the life cycle.

12           The U.S. needs an up-to-date nutrition  
13 and  
14 health status monitoring system to adequately  
15 determine policies and programs related to diet and  
16 health. Without such data, policies and education  
17 programs will never reach their potential.

18           On the question of research, NIH and  
19 other  
20 areas within DHHS and other research stakeholders  
21 and  
22 other research institutes in other departments,  
23 other  
24 research areas in academia as well as the medical  
25 community all have roles in biomedical and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 behavioral  
2 research related to health promotion and disease  
3 prevention.

4                   It is clear that both the food intake  
5 and  
6 energy expenditure parts of the equation must be  
7 addressed. For example, NIH's success in diabetes  
8 risk reduction resulted from education programs  
9 promoting physical activity. There should also be  
10 further examination of health care coverage. The  
11 federal government's Medicare and Medicaid programs  
12 could, at a minimum, highlight, pilot, and evaluate  
13 an  
14 efficacy of coverage for weight loss programs.

15                   You must also emphasize the role  
16 behavioral researchers must have in helping us  
17 solve  
18 this problem of how to eat as well as why as it  
19 relates to selection, portion control, exercise,  
20 and  
21 overall health.

22                   As stated, this complex multifaceted  
23 issue  
24 requires a multi-disciplined approach utilizing the  
25 expertise of all stakeholders. Asking all parties

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 involved to do their part in helping consumers  
2 better  
3 understand how to create healthful diets and  
4 include  
5 physical activity in their lives and the lives of  
6 their children is not a simple answer, but it is  
7 the  
8 right way to address this complex issue.

9           The food industry has a long history of  
10 providing consumers with safe and nutritious foods  
11 that meet the expectations for taste, value, and  
12 convenience.

13           The food industry responded to calls to  
14 create reduced, low, and non-fat food products and  
15 a  
16 variety of modified foods for specific dietary and  
17 medical needs. This was one of the first Healthy  
18 People 2000 objectives for the nation that was met.  
19 Innovation and reformulation are two key tenets in  
20 the  
21 food industry.

22           Revisions to the dietary  
23 recommendations  
24 and food guides are also needed since they, too,  
25 are

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 part of the solution. Just as it is important to  
2 define the state of scientific knowledge about diet  
3 and health and articulate national policy, we must  
4 also continue to improve the crafting of dietary  
5 guidance messages that are meaningful and  
6 actionable  
7 by consumers.

8 The key challenge will be to present  
9 the  
10 recommendations and information contained in the  
11 dietary guidelines, the food guide pyramid, and  
12 information on food labels so they actually  
13 motivate  
14 consumers to incorporate them into their daily  
15 lives  
16 and use them to create healthful diets and  
17 lifestyles.

18 Consumers need science-based  
19 information  
20 on how to eat as well as on what constitutes a  
21 healthful diet. The dietary guidelines are  
22 scientifically based, but they also must be easily  
23 understood, easily implemented, and trigger  
24 behavioral  
25 change with a focus on the guidelines dealing with

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 weight and physical activity. Triggering changed  
2 behavior by consumers will require input from  
3 behavioral scientists, a discipline not  
4 historically  
5 called upon for input on these guidelines. NFPA  
6 looks  
7 forward to when the dietary guidelines become the  
8 motivational tool that the American public so  
9 desperately needs.

10 In closing, let me quickly summarize  
11 NFPA's responses to the six questions posed; first,  
12 the available evidence. Again, as I mentioned, for  
13 some of the campaigns, it may still be too early.  
14 And  
15 time is absolutely essential to determine whether  
16 or  
17 not they work.

18 But, again, at the end of the day, the  
19 incidence of obesity and overweight continues to  
20 rise.  
21 We need to do more. We need to look within as well  
22 as  
23 outside our current areas of expertise to find  
24 examples that have worked in correcting other  
25 problem

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 areas and applying those methods and findings to  
2 this  
3 particular problem.

4 We can have different means to solving  
5 this problem. I personally believe that imitation  
6 is  
7 a serious form of flattery. And no one has ever  
8 been  
9 criticized for borrow good ideas.

10 Two, the priorities for nutrition  
11 research, particularly in children, of perhaps  
12 longitudinal studies that focus on the effects of a  
13 healthy start program are needed, utilizing  
14 traditional foods, new foods, a combination.  
15 Behavioral research, of course, is necessary as  
16 well.

17 We need to think outside of the box to  
18 help solve this problem and borrow against  
19 successes  
20 and intervention strategies from other areas and  
21 disciplines.

22 The behavioral-medical interventions.  
23 I've already mentioned the medical. But, again,  
24 let's  
25 look to lessons learned from other disciplines

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 focused  
2 on behavioral change, again national colostrual  
3 education program, and again messages that are  
4 conveyed in the elementary schools on environmental  
5 principles to children.

6 Change is needed to the food labeling.  
7 Switch the food label. Labeling alone will not  
8 affect  
9 this change, but it can help. It must be a  
10 combination of activities involving all  
11 stakeholders.

12 That said, the more information we can  
13 give consumers, the more information we are  
14 permitted  
15 to provide to consumers, information that is  
16 absolutely science-based and non-misleading, will  
17 allow consumers to become more knowledgeable in how  
18 they can better attain and maintain a healthy  
19 weight.

20 What opportunities exist for the  
21 development of healthier foods? As already stated,  
22 innovation and reformulation are two key tenets in  
23 the  
24 food industry, however reducing hurdles currently  
25 in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1 place as they relate to providing truthful and  
2 non-misleading information to consumers. And we  
3 applaud what FDA has done thus far, but there is  
4 still  
5 work to be done because there are still hurdles in  
6 place, particularly timing hurdles that prevent  
7 timely  
8 reviews of new ingredients and processes that would  
9 be  
10 helpful.

11 Further consumer demand is a key driver  
12 for new food product development. If consumers  
13 seek  
14 products with certain nutritional attributes, food  
15 companies will develop them. And consumers can't  
16 have  
17 that information unless that information can be  
18 provided to them.

19 Last, but not least, what's the most  
20 important things that FDA can do at this time?  
21 Again,  
22 flexibility in claims so consumers can get that  
23 information that they need and to lower the  
24 hurdles,  
25 make it more timely. Don't let us wait three or

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 four  
2 years in terms of an approval for an additive that  
3 is  
4 going to make a difference and is both safe and  
5 effective.

6 It is absolutely essential to work with  
7 consumers so they better understand what resonates  
8 with them. That is the key to motivation. And  
9 let's  
10 not assume that all consumers are the same.

11 Messages must be crafted. They must be  
12 targeted to the different segments and populations  
13 that make up the wonderful tapestry that is the  
14 American citizenry.

15 In summary, it has never been clear  
16 that  
17 government health professionals, educators,  
18 academia,  
19 industry, consumers, consumer groups must all work  
20 together to improve consumer education about how to  
21 eat and live a healthy lifestyle.

22 We hope that dialogues such as this  
23 today  
24 will help bring attention to the needs for  
25 nutrition

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 information and education and improvement in  
2 physical  
3 activity to promote the health of Americans and  
4 reduce  
5 this epidemic of obesity.

6           However, a note of caution is  
7 necessary.

8 It is absolutely essential that the first step to  
9 any  
10 type of focus and solution to a problem like this  
11 is  
12 to outline a plan. But a plan in the absence of  
13 action will get us nowhere in solving this very  
14 important problem.

15           We need to stay clear from "NATO." In  
16 this regard, I do not mean the North Atlantic  
17 Treaty  
18 Organization but, rather, a term I attribute to Dr.  
19 Judith Stern because I was on a panel and I was  
20 privileged to hear her use this term "NATO," which  
21 stands for No Action, Talk Only.

22           There's a lot of energy. There's a lot  
23 of  
24 motivation. There's a lot of focus on solving this  
25 problem. We must take the dialogues and the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 information that we glean from these types of  
2 discussions and apply them in terms of helping the  
3 American citizen.

4 Thank you.

5 (Applause.)

6 VICE CHAIRMAN LEVITT: Thank you very  
7 much.

8 Our second speaker and our final  
9 speaker  
10 before the break is Mr. Morgan Downey, Executive  
11 Director of the American Obesity Association,  
12 certainly appropriate for today.

13 MR. DOWNEY: Thank you. It's an honor  
14 to  
15 be here. It does always seem like I am always the  
16 last speaker before a meal function. So it's a  
17 little  
18 daunting.

19 I appreciate greatly this opportunity,  
20 and  
21 I appreciate greatly Secretary Thompson's  
22 enthusiastic  
23 commitment to the issue of obesity and the  
24 reflection  
25 of that throughout the Department of Health and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 Human  
2 Services.

3 We have submitted written comments,  
4 which  
5 addressed, in particular, the questions you have  
6 offered. In the interest of time, I would like to  
7 convey our paradigm for dealing with the obesity  
8 problem we have and then to recommend some specific  
9 changes which are under the jurisdiction of the FDA  
10 and others which are outside of the FDA but  
11 certainly  
12 the leadership represented in this room might want  
13 to  
14 be aware of.

15 What is our paradigm? First of all,  
16 obesity is not a behavior. Obesity is excess  
17 adipose  
18 tissue. And too often we confuse a behavior with a  
19 physiological state. Obesity is a disease because  
20 it  
21 meets any rational definition of a disease.  
22 Obesity  
23 is a fatal, chronic, relapsing disease that is at  
24 least as complicated to treat as heart disease or  
25 cancer.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   Obesity prevention and treatment  
2 include  
3 more than just diet and exercise as the  
4 effectiveness  
5 of these treatments over the long term has been  
6 poor.

7 Obesity is a global phenomenon arising from a  
8 combination of genetic, environmental, and  
9 behavioral  
10 factors. We do not know how to prevent or  
11 effectively  
12 treat obesity over the long term with the exception  
13 of  
14 bariatric surgery for persons with morbid obesity.

15                   If we do not drastically expand the  
16 research base in obesity and develop new  
17 treatments,  
18 our entire health care system is at risk. It is  
19 daunting to think how programs like Medicaid,  
20 Medicare, and private insurance can possibly absorb  
21 millions of new cases of ever younger and younger  
22 persons with co-morbid conditions brought about by  
23 obesity.

24                   Simplistic assertions that obesity is  
25 easily prevented or easily remedied do a disservice

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 to  
2 persons with obesity and inhibit the discovery of  
3 effective solutions.

4 In this regard, I would like to point  
5 out  
6 that frequently our discussions with the public  
7 health  
8 community have tended to focus, really, on  
9 prevention  
10 and let treatment ago.

11 I have had discussions with many  
12 leaders  
13 who say they really want to prevent obesity but not  
14 necessarily treat it. I think that is a mistake.  
15 I  
16 don't think in any other area of public health do  
17 we  
18 make that dichotomy. We don't say we only want to  
19 prevent SARS or West Nile and let treatment go.

20 We have a risk of overdoing it with the  
21 additional problem that we don't have prevention  
22 strategies on the shelf to implement. And so it is  
23 a  
24 dead end.

25 I also want to bring to your attention

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 an  
2 important fact. Sometimes in these discussions, we  
3 tend to focus on persons who are overweight or who  
4 just meet the BMI or other relevant cutoffs for  
5 obesity.

6 In fact, the real health problem is  
7 coming  
8 at the level of morbid or severe obesity,  
9 individuals  
10 who are 100 pounds or more overweight. These  
11 persons  
12 have tried repeatedly various diets and regimens  
13 for  
14 weight loss without success. This population in  
15 the  
16 United States is estimated at between eight and ten  
17 million. And just for purposes of comparison,  
18 that's  
19 two and a half or three times the entire  
20 Alzheimer's  
21 population in the United States.

22 Usually these persons have no access to  
23 insurance, no social or support networks, and the  
24 medical community is very ill-equipped to deal with  
25 them.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4100

www.nealr.com



1                   Let me go to some specific  
2 recommendations  
3 we have made in our written submission. Regarding  
4 food labeling, we think we need to get beyond the  
5 gaming that goes on in the nutrition label over  
6 portion size and calories.

7                   Packages should be labeled on the front  
8 in  
9 a clear, bold box with the total caloric content of  
10 the package that is for sale or the meal in the  
11 restaurant. We need to cut out the need to have a  
12 degree in nutrition and a calculator to figure out  
13 what one's caloric content is in one's daily life.

14                   Two, regarding the important role that  
15 the  
16 FDA plays in approval of drugs for the treatment of  
17 obesity, we are very hardened by the announcement  
18 this  
19 year from Commissioner McClellan for the  
20 development  
21 of new guidances for the treatment of obesity.

22                   Dr. Crawford met with a group of  
23 industry  
24 leaders that we convened from about 12-13  
25 pharmaceutical companies in April. Since that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrgross.com

1 time,  
2 the group has been developing specific  
3 recommendations  
4 for changes in the guidances.

5 We had a meeting a couple of weeks ago  
6 to  
7 finalize those as best we can. And we're ready, I  
8 think, in a couple of weeks to present them to the  
9 FDA  
10 and to sit down and to have a dialogue over some of  
11 the areas that the industry is interested in seeing  
12 improvements.

13 Third, we're concerned -- and we know  
14 the  
15 FDA has acted recently in the area of other drugs  
16 which cause weight gain. This is an important area  
17 particularly having to do with psychiatric  
18 treatment  
19 and drugs in that area.

20 However, overall the testing and  
21 information across the board in FDA approval of  
22 drugs  
23 tends to overlook the possibility that more and  
24 more  
25 medications might be contributing to weight gain.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   Regarding the approval of devices,  
2                   again,  
3                   throughout the FDA process, frequently devices have  
4                   not been tested in persons with obesity or are  
5                   physically not accessible to persons with obesity.

6                   And we may recall a few weeks ago a  
7                   terribly disturbing story of a morbidly obese  
8                   person  
9                   in the New York Times who could not physically fit  
10                  into the MRI machine and was recommended to go to  
11                  the  
12                  National Zoo for their MRI.

13                 Finally, we would like to see the FDA  
14                 increase their commitment to enforcement in the  
15                 dietary supplements and weight loss products areas.  
16                 We know they collaborate with the FTC, but we also  
17                 know that fraudulent weight loss products are the  
18                 largest health fraud in this country and, although  
19                 people are very dedicated, there's very little  
20                 enforcement or let's say there's a lot more  
21                 enforcement that needs to be done.

22                 Going broader to the HHS community at  
23                 large, we have recommendations for the creation of  
24                 a  
25                 national institute of obesity here at the National

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 Institutes of Health. This would be a tool to  
2 collect  
3 and advocate for more research funding for obesity  
4 from Congress as well as provide broad national  
5 leadership in addressing the confusion in the noise  
6 and the system about obesity.

7 We think HHS should look at its own  
8 house  
9 and to see whether it is organized to deal with an  
10 epidemic of this proportion. There is no office  
11 charge that I am aware of in HHS that has overall  
12 responsibility for coordinating the increasingly  
13 important and diverse efforts throughout the  
14 agencies,  
15 plus dealing with other federal agencies that have  
16 a  
17 stake in obesity.

18 We have also recommended that the  
19 centers  
20 for Medicare and Medicaid services speed their  
21 review  
22 of their policy determination that obesity is not a  
23 disease and, therefore, Medicare and Medicaid make  
24 no  
25 coverage for any treatments. This is under review

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1 with the Agency for Health Care Quality and  
2 Research.

3 We hope CMS moves quickly to provide  
4 leadership in this area and to incorporate the  
5 National Institutes of Health guidelines on the  
6 treatment of obesity into federal insurance  
7 programs,  
8 such as Medicare, Medicaid, and the Indian Health  
9 Service.

10 We have also proposed a couple of other  
11 techniques to improve our structural ability to  
12 deal  
13 with this epidemic. One is taking the page from  
14 the  
15 environmental movement, where the environmental  
16 impact  
17 statement had such a profound effect on raising  
18 awareness of the physical environment.

19 We are proposing a human activity or a  
20 human environment impact statement that would be  
21 attached as a requirement to federally funded  
22 transportation, construction, and other types of  
23 projects so that the planners, the architects, and  
24 the  
25 engineers would have to consider whether specific

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 projects are likely to increase or decrease the  
2 physical activity of the community affected and, if  
3 so, to at least have a neutral, if not a positive,  
4 impact on physical activity.

5           Finally, we have suggested as a concept  
6 that we look at encouraging the food industry to  
7 move  
8 more aggressively to use its substantial marketing  
9 prowess in a way that benefits more and more  
10 consumers  
11 dealing with obesity.

12           Our proposal would be to look at the  
13 corporate tax deduction for advertising expenses.  
14 These could be triaged into three categories: one  
15 that involves foods of high nutritional value and  
16 low  
17 calorie, for which companies could receive an  
18 incentive, two or three dollars in tax deduction  
19 for  
20 every dollar spent advertising those products; at  
21 the  
22 other end of the spectrum, foods of low nutritional  
23 value and high calorie, which would not receive any  
24 deduction at all, the products receive a one to  
25 one.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1                   We think, rather than regulation, some  
2 ways to incentivize the industry to be more  
3 proactive  
4 in promoting healthy lifestyles and nutritious  
5 products is a more effective and possibly more  
6 efficient way to go in the long term.

7                   Those are our recommendations. We look  
8 forward to working with the FDA working group in  
9 any  
10 way. Thank you.

11                   (Applause.)

12                   VICE CHAIRMAN LEVITT: Thank you very  
13 much. That magically brings us by the clock in  
14 front  
15 of me right to 11:30, when we said we would break  
16 for  
17 lunch.

18                   There are cafeterias in the building.  
19 And  
20 I would urge people to use them because by the time  
21 you leave and go out and get back, it will be hard,  
22 I  
23 think, to make it in the time we have allotted.

24                   One other announcement, and that is to  
25 those speaking this afternoon. A number of people

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 have audiovisual needs and have already provided  
2 them  
3 to the staff here. But if any speakers have  
4 audiovisual needs and you have not yet given them  
5 to  
6 the AV staff, please leave them at the desk on your  
7 way out for lunch.

8 With that, we will see everybody  
9 promptly  
10 at 12:30 back in this room.

11 (Whereupon, at 11:32 p.m., the  
12 foregoing  
13 matter was recessed for lunch, to  
14 reconvene at 12:37 p.m. the same day.)

15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25



1  
2  
3  
4  
5  
6  
7  
8

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(12:37

p.m.)

VICE CHAIRMAN LEVITT: I would like to welcome you all back after lunch, hopefully a healthy lunch. If you were not here this morning, my name is Joe Levitt. I am Director of the Center for Food Safety and Applied Nutrition and Vice Chair of the Obesity Working Group.

We will have on our agenda this afternoon a number of presentations by members of the public that are in the audience now. And at the end of that, if there are people who have not signed up but would like to have a short presentation from the floor from the microphone, we will make accommodation for that as well.

We will again follow the same schedule as

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 before, which is the speakers will come up  
2 individually up here to the podium. When you get  
3 up  
4 here, you will see a little clock with the amount  
5 of  
6 time that you have requested. And there are a few  
7 people in the break that asked for a few more  
8 minutes,  
9 not enough to get us off schedule. So don't worry.  
10 And you will see that clock. That clock will go  
11 down.  
12 And when there are two minutes left, the orange  
13 light  
14 will come on to give you the two-minute warning.

15           Again, we have a full and interesting  
16 agenda for this afternoon. So why don't we simply  
17 begin with our first speaker for the afternoon,  
18 Richard Black from the International Life Science  
19 Institute.

20           MR. BLACK: Good afternoon, everybody.  
21 Thanks very much, Joe. I would like to thank the  
22 FDA  
23 for actually orchestrating and organizing this  
24 meeting. I think it is very important.

25           I am going to ask a question of the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 committee, though. I don't know if it was better  
2 to  
3 be the last speaker before lunch or the first  
4 speaker  
5 after lunch.

6 I will ask seriously a question. The  
7 microphone's there. I thought the intent was for  
8 people in the audience to be able to question the  
9 speakers. You're not asking for that? Okay.

10 Let me tell you a little bit about ILSI  
11 North America. I work with ILSI North America, the  
12 International Life Sciences Institute. ILSI North  
13 America is part of a larger global group called  
14 ILSI.

15 We have branches literally around the world, about  
16 15  
17 branches in all, Europe, throughout Latin America,  
18 the  
19 Far East, North America, Mexico, and so on.

20 We are funded primarily by the food  
21 industry, by the consumer health care industry, by  
22 the  
23 pharmaceutical industry, and by the agricultural  
24 crop  
25 science industry. In addition, we also have

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 research  
2 institutes which are funded almost exclusively by  
3 government, either through the EPA or U.S. AID,  
4 Health  
5 Canada, and the European Commission.

6 As a 501(c)(3), we do not lobby. We do  
7 not advocate. We simply do science. We don't take  
8 a  
9 position on an issue. I have no position to offer  
10 you  
11 on obesity. You have all heard how complex it is,  
12 but  
13 I will advocate for science and the use of science  
14 in  
15 decision-making on obesity.

16 That's not to say that we have to wait  
17 until we have a perfect answer. I think the  
18 perfect  
19 answer is far too far away. But, nonetheless, I  
20 think  
21 the decisions that are made within trying to deal  
22 with  
23 the issue of obesity need to be informed by the  
24 science, the science at hand, and the science that  
25 is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 developing.

2 ILSI North America and the rest of the  
3 ILSI branches really stand for public-private  
4 partnership. That is the key message I think you  
5 should take home from this, from my presentation  
6 today.

7 We serve to bring together scientists  
8 from  
9 government, scientists from academe, and scientists  
10 from the food industry, the pharmaceutical  
11 industry,  
12 and the consumer health care industry meeting in a  
13 non-confrontational manner to solve issues of  
14 public  
15 health relevance that are equally important to all  
16 of  
17 those different sections.

18 As a result of this, we pride ourselves  
19 on  
20 credibility. We pride ourselves on not influencing  
21 the outcome of any particular study. The people  
22 that  
23 we contract with have the opportunity to do the  
24 work,  
25 publish the work. We encourage them to publish it.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 It is their work. It is their data. It is their  
2 patent if they get a patent out of it. Let's point  
3 to  
4 one because it is relevant for today.

5 This has just come out. I was given a  
6 copy of it yesterday. It's a supplement in the  
7 most  
8 recent Journal of Obesity Research, which is the  
9 North  
10 American Association for the Study of Obesity  
11 Journal  
12 on behavioral modification and societal change in  
13 the  
14 prevention of obesity. This was commissioned, a  
15 series of six papers commissioned, by one of our  
16 committees working on obesity.

17 I have included this slide, not for you  
18 to  
19 read it but more for the record. It's simply a  
20 list  
21 of those companies which are currently members of  
22 ILSI  
23 North America. I am presuming that these slides  
24 will  
25 be available to anybody off the Web site. So if

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 you  
2 want to see who our members are, you can easily do  
3 that.

4 This, for the same reason, is just a  
5 sampling of the kinds of groups with whom we have  
6 collaborated in the past, either sponsored meetings  
7 together or funding efforts that they have  
8 undertaken  
9 or they might hep fund efforts that we have  
10 undertaken, anything from the American Dietetic  
11 Association, FAO, Health Canada, the USDA, U.S.  
12 FDA,  
13 a whole host of different groups.

14 Let me just finish off by briefly  
15 telling  
16 you some of the initiatives that ILSI has ongoing  
17 around the world on obesity because, again, my  
18 understanding for this meeting was that FDA is  
19 interested in not only what is going on here in the  
20 U.S. or in North America but also what initiatives  
21 are  
22 taking place around the globe.

23 One of the initiatives that ILSI has  
24 underway, of course, is Take Ten, which was  
25 mentioned

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com



1 earlier this morning. It's an initiative through  
2 the  
3 Centers for Health Promotion based in Atlanta  
4 trying  
5 to integrate activity into the classroom. It is  
6 still  
7 undergoing evaluation for efficacy in terms of  
8 weight  
9 loss or weight maintenance or healthy weight gain.

10 We  
11 don't know the answer on that one yet.

12 We do have clear indications that it is  
13 going to or has shown increased time on task,  
14 decreased fidgeting in children. If you are going  
15 to  
16 sell something into the schools, you have got to  
17 tie  
18 it to education.

19 Teachers don't want to do this because  
20 it  
21 is going to help their kids lose weight. Teachers  
22 want to do something that is going to help the kids  
23 perform better in school. And if weight is an  
24 extra  
25 bonus, that's tremendous.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4100

www.nealr.com

1                   So when we think about interventions,  
2 we  
3 need to think about who is conducting intervention  
4 for  
5 us and what their win out of the intervention might  
6 be.

7                   We are also in the process of  
8 developing  
9 a partnership with PAHO, the Pan American Health  
10 Organization, part of the WHO, to look at  
11 interventions at the country level in three Latin  
12 American countries, Brazil, Chile, and Mexico, in  
13 terms of modifications in exercise, modifications  
14 in  
15 diet and doing a very thorough assessment of the  
16 impact on those three different studies to see if  
17 we  
18 can learn anything there that could be exported to  
19 either other developing countries where obesity is  
20 an  
21 issue -- I think it's an issue for different  
22 reasons  
23 in those countries than in North America -- or  
24 whether  
25 or not the findings from those are relevant for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 North  
2 America.

3                   Within ILSI North America itself, there  
4 are a number of projects underway as well. There  
5 have  
6 been projects in the past. To indicate what is  
7 going  
8 on currently is a real examination of lifestyle and  
9 lifestyle choices. This particular publication  
10 that  
11 I mentioned examines the dietary restriction  
12 method.

13 "Don't eat that." How effective truly is that in  
14 the  
15 long term?

16                   Models of behavior change. Can we  
17 learn  
18 anything from addictive behaviors, as in smoking?  
19 Can  
20 we learn anything from people who exercise to a  
21 great  
22 extent? Can we learn anything from behavior change  
23 models?

24                   And the last significant topic in this  
25 particular supplement dealt with our environment,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 which many people, of course, have called the  
2 obesogenic environment, trying to understand and  
3 summarize the literature as it exists to date.

4 We also have studies underway looking  
5 at  
6 fats, not just particular fat or tans fat or  
7 anything  
8 but a whole range of different dietary fats and  
9 looking at their satiating ability. Some fats or  
10 some  
11 macronutrients provide a greater feeling of  
12 fullness  
13 than others. And that's a relevant thing to know.  
14 It's an important thing to know.

15 We're also looking at carbohydrates,  
16 refined carbohydrates, their impact on weight,  
17 weight  
18 gain, weight loss, weight maintenance, looking at  
19 unrefined carbohydrates, whole grains, and dietary  
20 fiber, and, of course, glycemic response, which has  
21 generated a tremendous amount of interest going  
22 forward.

23 The last thing I want to mention and  
24 what  
25 we are trying to achieve with an ILSI -- and it

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

1 goes  
2 back to the role of ILSI North America in  
3 public-private partnerships -- is to bring people  
4 together who have an interest in this particular  
5 area.

6 We are hearing a lot from different  
7 consumer groups, different groups outside of the  
8 government today, but there are a whole range of  
9 government agencies involved in trying to  
10 understand  
11 this issue, trying to deal with this issue,  
12 deciding  
13 where to put money on this issue for funding, and  
14 so  
15 on.

16 If we can foster just a dialogue  
17 between  
18 those groups, which might be difficult to achieve  
19 otherwise, between the Department of Defense, which  
20 is  
21 spending huge amounts of money on this, with USDA,  
22 with FDA, with other groups within DHHS, if we can  
23 even serve that role, I think we are going a long  
24 way,  
25 bringing the Health Canada, the Canadians to some

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 health research. It's not trying to say what the  
2 answer is. It's trying to get people into  
3 agreement.

4 We're not on the negotiating table  
5 here.

6 We're all sitting on this side of the table. And  
7 the  
8 problem on the other side of the table is obesity.

9 I think that is what you are going to  
10 hear  
11 as the day goes on here as well. And that's the  
12 role  
13 that we're trying to play going forward with ILSI  
14 North America.

15 Thank you very much.

16 VICE CHAIRMAN LEVITT: Thank you.

17 (Applause.)

18 VICE CHAIRMAN LEVITT: Our next speaker  
19 is  
20 Dr. Craig Lefebvre.

21 DR. LEFEBVRE: Thank you.

22 Good afternoon. Yes, there are  
23 untoward  
24 effects of physical activity. I am a poster child  
25 for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 such an incident just recently. But after 45 years  
2 of  
3 being moderately to regularly intensively  
4 physically  
5 active, this is the first time I have to say I have  
6 ever had a problem like this. So it will not deter  
7 me  
8 from continuing in the future.

9 In that regard, I have been taken very  
10 good care of today by Brian and Darlene. I just  
11 want  
12 to let them know that I have been appreciating the  
13 fact I have been treated like a king here in my  
14 royal  
15 coach.

16 I want to thank the workgroup for the  
17 opportunity to address this important meeting that  
18 is  
19 focusing our nation's leading health hazard, the  
20 increasing problems of overweight and obesity among  
21 our nation's children and adults.

22 Reducing and preventing obesity is a  
23 major  
24 focus of the HHS Steps to a Healthier U.S.  
25 initiative.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 All HHS agencies and offices as well as many other  
2 government agencies have important roles to play in  
3 manning a comprehensive and sustained effort to  
4 address this issue.

5 My comments today come from a  
6 perspective  
7 of being a trained clinical psychologist. Dr. Phil  
8 was brought up earlier. I received my Ph.D. about  
9 two  
10 minutes before he did many years ago. And over the  
11 last 20 years, I have been conducting audience  
12 research to develop programs to improve nutrition  
13 and  
14 physical activity levels and ultimately to reduce  
15 and  
16 prevent obesity.

17 Some of those works included developing  
18 community-based programs, menu and shelf labeling  
19 systems, school and work site programs as part of  
20 the  
21 NHLBI-funded cardiovascular disease prevention  
22 study  
23 for the Heart Health Program back in the early  
24 '80s.

25 I was also involved with the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com



1 development  
2 and launch of the NCI's Five a Day for Better  
3 Health  
4 media campaign back in the early '90s. We also  
5 worked  
6 with the Department of Agriculture on the Team  
7 Nutrition Project, have done several projects with  
8 the  
9 CDC Branch of Nutrition and Physical Activity. And  
10 I  
11 have also over the years worked with a number of  
12 state  
13 and local health departments and other nutrition  
14 and  
15 physical activity initiatives.

16 So, from these experiences and also  
17 with  
18 a recent review of the literature, I would like to  
19 address, first of all, the first question, what is  
20 the  
21 available evidence on the effectiveness of various  
22 educational campaigns?

23 There is a substantial body of evidence  
24 published in a variety of places that suggest that  
25 many different kinds of behavior change

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 methodologies  
2 applied in specific settings, such as schools and  
3 work  
4 sites, can have a positive, if short-term, impact  
5 on  
6 dietary and physical activity habits.

7           Community-based activities, such as  
8 Kentucky, Stanford, and Minnesota, have also been  
9 shown to be effective in reducing weight among  
10 participants in such programs, although  
11 population-wide where public health goals for  
12 reducing  
13 the prevalence of overweight and obesity have not  
14 been  
15 consistently demonstrated.

16           I think the public health challenge  
17 that  
18 face the HHS and FDA is the reduction in the  
19 prevalence of obesity among all Americans. And I  
20 stress the "all."

21           When agencies undertake such  
22 large-scale  
23 interventions, they often look at health  
24 communications and social marketing methods to  
25 develop

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 strategies and tactics. I want to briefly review  
2 the  
3 effectiveness of these approaches in nutrition and  
4 physical activity.

5 Rina Alcalay and Robert Bell recently  
6 reviewed over 50 community campaigns that were  
7 aimed  
8 at increasing physical activity and improving  
9 nutrition. These campaigns showed several  
10 characteristics, including targeting one or more  
11 communities of people and employing multiple health  
12 promotion activities across multiple communication  
13 channels; that is, they were not site-specific.

14 Nearly 70 percent had behavioral  
15 objectives related to reducing consumption of fat,  
16 62  
17 percent sought to increase levels of physical  
18 activity, 60 percent attempted to increase fruit  
19 and  
20 vegetable intake, and 28 percent of these 50  
21 studies  
22 focused on reducing caloric intake. Over half of  
23 these studies focused on both addressing nutrition  
24 and  
25 physical activity messages.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1                   While the authors of this summary did  
2 not  
3 attempt to review all of the outcomes of all of  
4 these  
5 studies, their analysis of the strategies and  
6 practices that were employed in these campaigns or  
7 not  
8 led them to the following recommendations for  
9 future  
10 efforts, which I would encourage the Working Group  
11 to  
12 consider in their deliberations.

13                   The first of these recommendations is  
14 that  
15 formal behavioral change theories should be  
16 utilized  
17 by program planners from the time that they begin  
18 to  
19 set objectives until they evaluate their outcomes.

20                   The second is that program objectives  
21 should be formulated in precise and measurable  
22 goals.

23                   The third point is that formative  
24 research  
25 to understand consumer needs, motivations,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 practices,  
2 and beliefs should be conducted early in the  
3 planning  
4 process and could be complemented by concept  
5 testing  
6 and message pre-testing before material production  
7 and  
8 implementation.

9 Fourth, efforts to segment audiences  
10 should go beyond demographics to include  
11 psychographic  
12 information, lifestyles, ethnicity, and  
13 inculturation  
14 factors.

15 And the fifth recommendation was a  
16 social  
17 marketing frame, which should be more explicitly  
18 used  
19 and incorporated into all program designs and  
20 development.

21 The second point I would like to bring  
22 out  
23 is one related to research we did as part of the  
24 USDA's Team Nutrition project. In the four school  
25 districts where we did this pilot intervention,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 one-half of the schools were randomly assigned to  
2 treatment to implementing nutrition. And the other  
3 half became comparison sites who conducted no  
4 interventions during the semesters in which the  
5 evaluation took place.

6 Approximately 1,650 fourth graders were  
7 eligible to participate in each phase of this  
8 study.

9 And they were equally divided between the  
10 intervention  
11 and comparison school sites.

12 We developed a series of curricula for  
13 elementary grades, particularly three through five,  
14 eight to nine lessons that contain teachers'  
15 guides,  
16 classroom and cafeteria activities, videos,  
17 posters,  
18 student magazines, and parent take-home pieces.

19 All  
20 of that detail becomes important in a minute, by  
21 the  
22 way.

23 In addition, schools also had to commit  
24 to  
25 having their teachers trained, their cafeteria food

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 service staff trained, and modifying their food  
2 service offerings to comply with the new USDA  
3 school  
4 meals initiative.

5 Also, the school had to be involved in  
6 a  
7 set of four activities, including two school-wide  
8 cafeteria events during each semester, conducting  
9 at  
10 least three parent contact activities for these  
11 students each semester, having at least two chef  
12 activities, having at least one district-wide Team  
13 Nutrition event, and conducting at least one  
14 district-wide media event.

15 In addition, we also worked with the  
16 Disney Corporation to develop a series of public  
17 service announcement, which were also aired in  
18 these  
19 communities on the Disney cable channels.

20 In essence, the intent of this  
21 intervention was to treat a true surround sound  
22 environment in these schools and communities to not  
23 only support individual change, both at the child  
24 level, the teacher level, and the parent level, but  
25 also to try and facilitate normative changes

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 related  
2 to child nutrition in those schools and in those  
3 communities.

4           The rest of this pilot evaluation  
5 suggested that team nutrition did lead to modest  
6 but  
7 significant changes in self-reported behavior  
8 change,  
9 but the important idea in the study came from our  
10 analysis of which components of the intervention I  
11 just described were associated with the reported  
12 behavior change.

13           Our conclusion was that it was exposed  
14 to  
15 multiple Team Nutrition components, not simply the  
16 curriculum, not simply changes in the cafeteria,  
17 not  
18 simply take-home information for parents, but the  
19 accumulation of exposures that were most predictive  
20 of  
21 behavior change.

22           Indeed, the degree of self-reported  
23 behavior change was directly related to a number of  
24 channels students reported being exposed to Team  
25 Nutrition messages during the intervention.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com



1           As the FDA considers potential roles to  
2 play in addressing the obesity problem, I would  
3 encourage you to consider the unique channel and  
4 opportunity you have to amplify and reinforce  
5 messages  
6 related to improving dietary and physical activity  
7 behaviors, which leads me to address briefly  
8 question  
9 number 6, recommendations for efforts that FDA  
10 might  
11 take to address problems of overweight and obesity.

12           So building on these experiences and  
13 these  
14 data, I believe that the FDA should not consider  
15 putting its resources into targeted or mass public  
16 health communications campaigns using traditional  
17 media channels. Rather, I suggest that looking at  
18 how  
19 communications media that the FDA is uniquely  
20 suited  
21 to influence be used to complement and amplify  
22 nutrition and physical activity messages coming  
23 from  
24 other HHS and government agencies to achieve the  
25 surround sound environment so that Americans can

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1 improve their health.

2 In particular, I want to encourage the  
3 working group and the FDA to consider how food  
4 labels  
5 can be better used to encourage not only better  
6 nutrition choices on the caloric intake side of the  
7 equation but to present the caloric expenditure  
8 side  
9 of the weight equation, physical activity, and,  
10 thus,  
11 improve the nutrition label from one focused on  
12 simply  
13 nutrition information to one that provides health  
14 information.

15 My rationale for adding physical  
16 activity  
17 information to food labels includes, first, as many  
18 consumer research studies that I have conducted and  
19 others have conducted over the past few years  
20 consistently showed that children, teenagers, and  
21 adults readily put nutrition and physical activity  
22 together, often over the idea of improving their  
23 health and, more importantly, having more energy.

24 We need to take advantage of this  
25 natural

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 occurrence and utilize every opportunity to  
2 reinforce  
3 to these audiences the energy balance message,  
4 rather  
5 than artificially separating them into just  
6 nutrition  
7 or just the physical activity ones.

8           The second point is that  
9 point-of-choice  
10 promotions do reach and affect a substantial number  
11 of  
12 consumers with regard to the purchase behaviors and  
13 health knowledge.

14           When consumers are purchasing food  
15 items,  
16 they're often more open to and aware of food and  
17 health-related information. We need to take  
18 advantage  
19 of this critical opening by not simply piling more  
20 nutrition onto labels but grabbing their attention  
21 through the addition of physical activity messages  
22 in  
23 ways that are relevant to their lives.

24           Some possible ways to do this might be  
25 to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 balance the caloric message with examples of how  
2 much  
3 physical activity, such as walking, would be needed  
4 to  
5 "balance" the caloric content of food items.

6 Another potential strategy would be to  
7 rotate examples of moderate levels of physical  
8 activity along with the Surgeon General's  
9 guidelines  
10 for physical activity, much the same as is done  
11 with  
12 tobacco products.

13 A third option to explore would be for  
14 the  
15 FDA to work with food companies to develop physical  
16 activity and nutrition initiatives that take  
17 advantage  
18 of product packaging and advertising, as they did  
19 with  
20 co-ops, in promoting the link between dietary fiber  
21 intake and cancer.

22 These are just a few examples of how I  
23 see  
24 the FDA making a substantive and unique  
25 contribution

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 to combat a national epidemic of obesity. I would  
2 be  
3 happy to discuss these and other ideas with the  
4 workgroups if they desire to follow up on these  
5 things.

6 My final word of caution from comments  
7 made this morning is also that when we talk about  
8 delivering messages, there is an old saying passed  
9 around in some public health textbooks that I  
10 always  
11 keep my staff in the front of their minds. And  
12 that  
13 is that public health professionals have messages,  
14 but  
15 people have lives. And I think we need to spend  
16 more  
17 time understanding and responding to people's lives  
18 than listening to and responding to our own  
19 messages.

20 Thank you very much for your time.

21 (Applause.)

22 VICE CHAIRMAN LEVITT: Thank you very  
23 much.

24 Our next speaker is Nisha Patel with  
25 the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 Girl Scouts of America.

2 MS. PATEL: Good afternoon. I'm  
3 representing the Girl Scouts of the USA this  
4 morning.

5 GSUSA has their primary focus on fighting obesity.  
6 GSUSA has a 91-year history of helping girls lead  
7 healthy and productive lives. We are committed to  
8 encouraging healthy, active lifestyles to prevent  
9 obesity and create confident, powerful young  
10 leaders  
11 of today.

12 The key factor is education. We  
13 produce  
14 many programs that teach girls, our girls, how to  
15 live  
16 healthy lives, healthy eating, and increase their  
17 physical activity in everyday lifestyles.

18 A few of the programs that we have are  
19 Girlsports. Girlsports is a nationwide program  
20 that  
21 increases sports, fitness, and increases ideas of  
22 healthy eating and how all of these concepts work  
23 together.

24 Another program we have is Uniquely Me.  
25 We work with girls on increasing self-esteem, body

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 image, and tying in food as energy for girls.

2 Strong Bones, Strong Girls is another  
3 program that we work with the CDC increasing bone  
4 health and the importance of calcium as well as  
5 healthy eating and physical activity.

6 We are recently just putting together a  
7 proposal to fight childhood obesity and have been  
8 working on a nationwide campaign to work with CDC,  
9 Unilever, USDA, FDA, and other organizations to  
10 find  
11 funding and find a big nationwide program that will  
12 affect girls and boys nationwide.

13 Some of the research needs that we have  
14 come across are the need to work with after-school,  
15 weekend, and camping activities to see what works,  
16 what gets through to our youth and teens today.

17 We have our own research institute  
18 called  
19 the Girl Scouts Research Institute. They're in the  
20 midst of a comprehensive review and research on  
21 childhood obesity and activity that will be  
22 available  
23 to anyone in Spring 2004.

24 Thank you.

25 (Applause.)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1                   VICE CHAIRMAN LEVITT: Thank you very  
2 much, very direct and succinct.

3                   Our next speaker is Laurie Tansman with  
4 the Department of Nutrition at Mount Sinai  
5 Hospital.

6                   MS. TANSMAN: While I'm giving him a  
7 second to go upstairs, I want to preface my  
8 comments  
9 by saying that my presentation and my commentary  
10 and  
11 recommendations are based upon my professional  
12 scope  
13 of experience and my frustrations. So please don't  
14 be  
15 angry at me if some of it may seem critical or seem  
16 a  
17 little off the wall.

18                   I am going to address four questions,  
19 two  
20 of which are combined. I think the fact that we  
21 are  
22 here today speaks of the lack of effectiveness of  
23 the  
24 campaigns that we have, but, quite frankly, the  
25 first

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4100

www.nealrsgross.com



1 thing I have to say is what education campaigns.  
2 There is an abundance of information that is out  
3 there, but is this information reaching the average  
4 Americans, especially those who do not have  
5 internet  
6 access?

7 I think that we need to have a unified  
8 national program. We don't have that as there is,  
9 for  
10 example, to promote fruit and vegetable consumption  
11 via five a day, which is now known as Five to Nine  
12 a  
13 Day.

14 What we do have is a plethora, as I  
15 always  
16 like to say, a variety of information that is out  
17 there. But especially I want to call your  
18 attention  
19 to the last point, a small but growing number of  
20 health insurance providers encouraging wellness  
21 activities and weight control with awarded  
22 incentives  
23 as well as dieticians at the other end of the phone  
24 to  
25 provide individualized weight loss counseling, as

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 addressed in an article this past week in the Wall  
2 Street Journal entitled "Winning by Losing."

3           What we don't have, though, is massive  
4 public advertising education campaigns, such as  
5 billboards on highways, placards on buses, public  
6 service announcements on radio and television,  
7 although the closest we do have to it is on the  
8 youth  
9 media campaign entitled VERB from the CDC, which we  
10 heard about earlier this morning.

11           And most especially and not just  
12 because

13 I am a registered dietitian, we don't have a  
14 significant amount of insurance reimbursement for  
15 the  
16 prevention and treatment of overweight and obesity  
17 as  
18 provided by registered dietitians, the nutrition  
19 experts, or for participation in a recognized and  
20 reliable weight control program, such as Weight  
21 Watchers.

22           As stated in that same article from the  
23 Wall Street Journal on Tuesday, "While the  
24 insurance  
25 industry is becoming more active, many companies

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 often  
2 pay little or nothing for weight control practices.  
3 If we are going to get serious about addressing the  
4 dearth of this country, then we must change.  
5 Insurance reimbursement is a must."

6 And a final thought before moving on --  
7 and I didn't know where to put it in this  
8 presentation. So I put it right over here. In the  
9 process of adapting educational strategies which  
10 are  
11 ethnic-specific, we should not let cultural  
12 sensitivities to differences in the definition of  
13 what  
14 is a healthy weight interfere with the message.

15 In fact, in communities where the  
16 definition of an ideal body weight/healthy body  
17 weight  
18 is more than it should be, the authors of -- and  
19 this  
20 is a mouthful; it was an article -- the differences  
21 in  
22 body shape representation among young adults from a  
23 biracial, black/white, semi-world community that  
24 just  
25 appeared in the current issue of the American

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4100

www.nealr.com

1 Journal  
2 of Epidemiology recommended that future research  
3 should focus on helping such communities "get an  
4 understanding of healthy body shapes and the risks  
5 associated with accepting a heavier body image."

6 My final comment in this section, in  
7 the  
8 current issue of Prevention magazine for November,  
9 there is an outstanding article that is featured on  
10 the cover about how to fat-proof your child.  
11 Within  
12 the article, two moms and three or four different  
13 children are pictured. They're all white. And  
14 that  
15 bothered me because this is a concern that should  
16 be  
17 especially directed to all parents of all colors.

18 The next two questions I actually kind  
19 of  
20 address together. I think what the FDA can be  
21 instrumental in addressing is the establishment of  
22 a  
23 national public and private partnership between the  
24 government and the food, diet, exercise industry  
25 akin

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 to the five-a-day program and that will support  
2 massive public education.

3 This collaboration I think will  
4 especially  
5 be conducive to getting things done, especially  
6 information on packaged foods, speaking of which I  
7 think we need to have warning labels on foods, such  
8 as  
9 the example that I give here.

10 I also read on my professional listserv  
11 the other day from the Myrtle Beach Sun News on  
12 October 18th there was an article reviewing a  
13 nutrition conference in South Carolina from the  
14 previous day, which included reference to the fact  
15 that warnings presumably on packaged foods might  
16 help  
17 people make better choices about nutrition. And  
18 the  
19 warning that was quoted in this article was  
20 "Caution:  
21 To work off the calories on this hamburger, you'll  
22 have to walk six miles." I think that was  
23 fabulous.

24 Last but not least, question number  
25 two.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 I didn't do this in order. What are the top  
2 priorities for nutrition research to reduce  
3 overweight  
4 in children? I have to tell you, whether it's in  
5 the  
6 hospitals, the outpatient, in the community, or my  
7 private practice, it's how to engage parents to be  
8 role models for their children.

9 This was a statement that I was asked  
10 to  
11 provide. There's an upcoming program this Monday  
12 evening on ABC. I think it's at 8:00 o'clock.  
13 It's  
14 being cosponsored with Prevention magazine. This  
15 says  
16 it all. So I am not going to read that whole thing  
17 other than to say children live what they learn.  
18 And  
19 you just can't say to children, "Don't do as I do.  
20 Do  
21 as I say."

22 And from that same article in  
23 Prevention  
24 magazine I just want to read to you, the subtitle  
25 was

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 "There's a secret weapon to help keep your kids  
2 slim  
3 in a supersize world: YOU."

4 But, finally, now, what can the FDA do  
5 about this? Well, again, I think in collaboration  
6 with the food industry, it is to encourage parents  
7 to  
8 be role models and, again, messages on packaged  
9 food,  
10 the importance of everyone in the family having a  
11 well-balanced breakfast in the morning along with  
12 what  
13 compromises a well-balanced meal.

14 That concludes my presentation. And I  
15 thank the FDA for including me on their agenda with  
16 such distinguished speakers.

17 (Applause.)

18 VICE CHAIRMAN LEVITT: Thank you. And  
19 as  
20 someone who is personally audiovisually challenged,  
21 I  
22 appreciate the need for assistance.

23 Our next speaker is Dr. Barbara Moore,  
24 President and CEO of Shape Up America!

25 DR. MOORE: Thank you for providing me

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

1 with this opportunity to address the panel today.  
2 I'm  
3 Barbara Moore, the President of Shape Up America!  
4 But  
5 I think that I am going to sort of step back and  
6 give  
7 you a little bit of information about my  
8 background.

9 I used to have a BMI of 30, which is,  
10 of  
11 course, the threshold for the definition of  
12 obesity.

13 I lost my weight in the 1970s. I had been a  
14 philosophy major in college. And I went to work  
15 for  
16 Mobil Oil Corporation as a secretary. I sat at the  
17 desk and took advantage of the coffee carts and the  
18 highly subsidized lunches at Mobil Oil Corporation  
19 in  
20 New York City at that time, and I became fat.

21 I went to Weight Watchers. And I lost  
22 my  
23 weight. And I became interested in nutrition and  
24 in  
25 obesity as a consequence of that personal

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com



1 experience.

2 And so I decided to go back to college.

3 I went to Columbia School of General  
4 Studies. And I acquired all of my necessary  
5 science  
6 courses to become a candidate for the Master's  
7 program  
8 in nutrition at Columbia University and eventually  
9 a  
10 Ph.D.

11 I did all of my research at Columbia in  
12 obesity, including childhood obesity, back then in  
13 the  
14 '70s. And I did my post-doctoral research for four  
15 years at the University of California at Davis.  
16 And  
17 then I became a professor of nutrition at Rutgers  
18 on  
19 a tenure track for several years. And, all of a  
20 sudden, I get a phone call from a head hunter  
21 representing Weight Watchers.

22 So I bid my colleagues at Rutgers  
23 adieu.

24 And I went to Weight Watchers. I was responsible  
25 for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 the Weight Watchers program from 1989 to 1993, at  
2 which point I came to Washington, D.C.

3 And I worked in the Office of Science  
4 and  
5 Technology Policy for a couple of years. I worked  
6 at  
7 the NIH in the NIDDK. And I was back at the White  
8 House in 1995 when I got a phone call from C.  
9 Everett  
10 Koop, asking me if I would be willing to run Shape  
11 Up  
12 America! for him. So I sort of pinched myself and  
13 said, "You bet. I'll be there except I've made  
14 some  
15 promises, and I have to keep them."

16 He said, "Well, how many months is it  
17 going to take you?"

18 I said, "Oh, about five."

19 He said, "Okay. I'll see you in five  
20 months." So I've been with Shape Up America! ever  
21 since.

22 Basically I am here today to talk to  
23 you  
24 a little bit about the founding of Shape Up  
25 America!;

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 its mission; the targets of the campaign; and what  
2 I  
3 think is some evidence of its impact. And I'll  
4 summarize it for you.

5 To give you the background on the  
6 founding  
7 of the organization, Dr. Koop was Surgeon General  
8 from  
9 1981 to 1989. So he was in "retirement" when he  
10 founded Shape Up America! in 1994.

11 It grew. The campaign grew out of  
12 Healthy  
13 People. In those days it was Healthy People 2000.  
14 Now, of course, we're working on Healthy People  
15 2010.

16 Basically he was interested in addressing  
17 overweight  
18 and obesity as a health issue. It had been framed.

19 I must tell you back then in the '90s,  
20 in  
21 the mid '90s, there was a very strong anti-diet  
22 movement in the United States. There was a growing  
23 fat acceptance movement in the United States. And  
24 it  
25 was very difficult to frame obesity as a health

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 issue.

2 There were very few of us out there doing that at  
3 that  
4 time.

5 So the mission of Shape Up America! was  
6 to  
7 raise awareness, public awareness, of obesity as a  
8 health issue and I must say professional awareness  
9 of  
10 obesity as a health issue, rather than a cosmetic  
11 issue.

12 Dr. Koop wanted us to provide  
13 responsible  
14 information on weight management to the public, to  
15 health care professionals, to educators. And that,  
16 by  
17 all means, includes the media as well as  
18 policy-makers. And that includes not just  
19 government  
20 employees but also work site employers and I would  
21 say  
22 parents. So I would agree with the previous  
23 speaker  
24 that parents are policy-makers.

25 We have produced over the years a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 number  
2 of consumer brochures. The first one we produced  
3 is  
4 called "On Your Way to Fitness." I have given a  
5 copy  
6 of every consumer brochure that we have produced to  
7 Patricia Alexander, and I happy to supply  
8 additional  
9 copies if you need them.

10 This particular brochure is interesting  
11 because we managed to distribute well over five  
12 million copies of this brochure to the public. We  
13 had  
14 at one point 800 numbers. We had it incorporated  
15 in  
16 patient education kits.

17 Oh, I forgot to mention where the  
18 funding  
19 for Shape Up America! came from. It primarily came  
20 from the weight loss industry, from the  
21 pharmaceutical  
22 industry, food industry, and to a limited extent  
23 consumer products industry, but we also have gotten  
24 a  
25 few grants from foundations.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   So in this case, the Wyeth-Ayers  
2 Company  
3 had just bought a drug approved by the FDA. It was  
4 called dexfenfluramine. It was marketed under the  
5 name of Redux. They found out about this little  
6 brochure, and they put it in their patient  
7 education  
8 kit. That's how we were able to reach so many  
9 people  
10 with that brochure.

11                   Rina Wayne came to me about five years  
12 and  
13 asked me if I would donate 5,000 copies of "On Your  
14 Way to Fitness" to the diabetes prevention program,  
15 which was just ramping up at that time. You may  
16 know  
17 that the results of that DPP were published in the  
18 New  
19 England Journal of Medicine last year. And this  
20 brochure was used in all three arms of the study  
21 that  
22 were described in the New England Journal of  
23 Medicine  
24 article and weight loss was achieved in all three  
25 of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 those arms.

2 In 1995, we launched our Know Your BMI  
3 campaign. The reason we did that is because there  
4 was  
5 very good evidence that the body mass index  
6 correlated  
7 rather well with the amount of body fat in the  
8 human  
9 body. So it was considered a preferable indicator  
10 of  
11 health over weight, over the use of weight.

12 So we spent, I would say, \$2 million on  
13 our Know Your BMI campaign. I will tell you that  
14 when  
15 the campaign started, journalists would say, "You  
16 can't use that phrase 'Body Mass Index, BMI.' You  
17 have to tell me what this means in terms of pounds  
18 overweight." So we have come a long way since we  
19 launched this campaign.

20 Body mass index, or BMI, is now a term  
21 in  
22 common usage, I would argue, by the public and also  
23 by  
24 the health care professional community as well as  
25 the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 media.

2 We published the first evidence-based,  
3 quality-ranked -- that's the evidence was  
4 quality-ranked. It was a book designed for health  
5 care professionals called "Guidance for Treatment  
6 of  
7 Adult Obesity." We published it in 1996. It dealt  
8 with all of the co-morbidities of obesity, and it  
9 dealt with all treatment modalities, including  
10 surgery  
11 and pharmacotherapy. We distributed more than  
12 200,000  
13 copies of that document between the years 1996 and  
14 1998.

15 Now, in 1998, the NIH published its  
16 guidance on the treatment of adult obesity. And I  
17 will tell you that that document started out  
18 narrowly  
19 focused on cardiovascular disease. I believe that  
20 as  
21 a consequence of our effort to expand the scope of  
22 the  
23 document -- and there were some dialogues back and  
24 forth between Dr. L'Enfant and Dr. Koop -- I  
25 believe

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1 that we had an influence on expanding the scope of  
2 the  
3 NIH document to include all co-morbidities of  
4 obesity.

5 I consider that an important accomplishment of  
6 Shape  
7 Up America!

8 In 2000, we published the third edition  
9 of  
10 the guidance document and in a CD-ROM version. I  
11 went  
12 on a lecture tour to medical schools last year.  
13 And  
14 I visited 24 different medical institutions and  
15 distributed several thousand more copies of the  
16 guidance document.

17 With respect to the media, we produced  
18 over the years a number of public service  
19 announcements on the health risks of overweight, on  
20 the role of physical activity in weight management,  
21 in  
22 addition to Know Your BMI. These PSAs ran on TV  
23 and  
24 radio stations across the nation between 1996 and  
25 2001.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   We held six press conferences in New  
2                   York  
3                   City and Washington, D.C. We developed a press  
4                   release program. We developed evergreen pieces for  
5                   use in print media. We spent at least four and a  
6                   half  
7                   million dollars that I was able to count up. And  
8                   these messages reached well over 40 million  
9                   households  
10                  in that period of time.

11                  Our Web site was launched in 1996.  
12                  Almost  
13                  since the day it was launched the unique visitors  
14                  to  
15                  the site per month ranged anywhere from 60,000 to  
16                  220,000. And we ran a survey of the users of our  
17                  Web  
18                  site.

19                  Fifty-eight percent of them reported  
20                  positive behavioral changes with respect to eating  
21                  fruits and vegetables and/or physical activity.  
22                  And  
23                  the survey was of several thousand people, who were  
24                  users of our Web site.

25                  In 2001, we launched an initiative to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 address the connection between obesity and Type II  
2 diabetes. We call this our diaobesity initiative.

3 We  
4 had a national conference here in Washington, D.C.  
5 in  
6 2001. And we are launching a second national  
7 conference at Rutgers University next month.

8 On the topic of childhood obesity, I  
9 will  
10 tell you that we have done precious little. The  
11 first  
12 reason why we haven't done very much is because I  
13 knew  
14 that the CDC was revising the pediatric growth  
15 charts  
16 and that they came out in the year 2000. I felt it  
17 was important to wait for those charts to become  
18 available before we did much of anything.

19 And then the whole problem of childhood  
20 obesity started to mushroom and the awareness of  
21 this  
22 problem. And the connection between pediatric  
23 obesity  
24 and Type II diabetes started to mushroom. Before  
25 you

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 know it, the Institute of Medicine convened a panel  
2 to  
3 address childhood obesity and develop an action  
4 plan.

5 I was appointed to that panel earlier this year.

6 I think the appropriate thing to do is  
7 to  
8 wait for the IOM report to come out and to shape an  
9 initiative that addresses childhood obesity that is  
10 guided by the Institute of Medicine document.  
11 That's  
12 the plan for Shape Up America!

13 I agree, by the way, with the previous  
14 speaker that parenting is really fundamental to  
15 addressing the problem of childhood obesity. We  
16 are  
17 in the process of designing a conference to be held  
18 in  
19 Washington, D.C. on December the 8th that will be  
20 focusing on very early childhood factors, starting  
21 with pregnancy and ending with preschool. That  
22 conference will be on an invitation-only basis.  
23 And  
24 the invitations will be going out next week.

25 We're going to be publishing the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 proceedings of that conference. We're not sure  
2 exactly where it is going to be published, but  
3 we're  
4 in discussions to ensure that that happens. And,  
5 as  
6 I said, our plans for childhood obesity will be  
7 guided  
8 by and shaped by the IOM document once it becomes  
9 available.

10 In conclusion, Shape Up America! is  
11 well-established and trusted as a brand. It is  
12 able  
13 to garner media attention and to educate consumers  
14 and  
15 health care professionals in a variety of ways. We  
16 welcome partnerships to leverage communication  
17 around  
18 obesity, health, and fitness messages.

19 That concludes my remarks. Thank you  
20 for  
21 your attention.

22 (Applause.)

23 VICE CHAIRMAN LEVITT: Thank you very  
24 much.

25 Our next speaker is David Martosko,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 Director of Research, the Center for Consumer  
2 Freedom.

3 MR. MARTOSKO: Thank you very much.

4 Good afternoon. My name is David  
5 Martosko, and I run the Research Program at the  
6 Center  
7 for Consumer Freedom here in Washington. We are a  
8 nonprofit coalition of restaurant operators, food  
9 companies, and concerned individuals. And we work  
10 together to promote the idea of personal  
11 responsibility and to protect consumer choices.  
12 And

13 I thank you very much for the opportunity to  
14 address  
15 this committee.

16 Obesity is a genuine problem in  
17 America,  
18 but our national debate on the subject has become  
19 nothing short of hysterical. And around every  
20 corner  
21 is a hidden agenda.

22 Pharmaceutical interests, like the  
23 American Obesity Association, which we heard from  
24 earlier, promote an alarmist view of the problem in  
25 order to justify increased government support and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 promotion of new obesity drugs.

2 Animal rights groups, like the  
3 deceptively  
4 named Physicians Committee for Responsible  
5 Medicine,  
6 whose president will speak shortly, like to inflate  
7 the public's obesity fears in order to disparage  
8 beef,  
9 chicken, pork, milk, cheese, and any other foods  
10 that  
11 are not animal rights-friendly.

12 And then, of course, there are the  
13 radical  
14 nutrition activist groups, like Center for Science  
15 in  
16 the Public Interest, which never met a tasty food  
17 it  
18 couldn't talk about and whose leaders seldom pass  
19 up  
20 a chance to announce a desire to tax foods they  
21 don't  
22 like out of ordinary Americans' reach.

23 CSPI, in particular, Center for Science  
24 in  
25 the Public Interest, has recklessly tried to link

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 food  
2 to tobacco in deliberate scare campaigns.  
3 Trial lawyers, of course, are  
4 attempting  
5 to turn America's love of good food into the next  
6 cash  
7 cow. And here is John Banzhaf, the leading attack  
8 dog, saying that a fast food company "may not be  
9 responsible for the entire obesity epidemic, but  
10 let's  
11 say they're five percent responsible." Thus, says  
12 the  
13 lawyer, "Five percent of \$117 billion is still an  
14 enormous amount of money." And we know where he is  
15 coming from.

16 Likewise, activists and some academics  
17 have proposed zoning restrictions and other rather  
18 draconian regulations on restaurants. Here is an  
19 author in Washington Monthly saying that we should  
20 zone restaurants away from schools, regulating the  
21 location, density, and hours of what they call  
22 "junk  
23 food outlets."

24 Now, we believe that the nation would  
25 be

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com



1 better served by a serious and scientific approach  
2 to  
3 addressing obesity. I hope that's what we're  
4 engaged  
5 in here today.

6 As the FDA begins to build a framework  
7 for  
8 messages to the public about weight reduction, it  
9 is  
10 vitally important to avoid inadvertently  
11 exaggerating  
12 or misrepresenting the problem and steering clear  
13 of  
14 needless hyperbole can be as simple as checking  
15 your  
16 facts and figures.

17 The three most commonly cited  
18 statistics  
19 associated with the obesity epidemic are: number  
20 one,  
21 that obesity causes 300,000 deaths per year in  
22 America; two, that 61 percent of Americans are  
23 overweight or obese; and, three, that the economic  
24 cost of American obesity is \$117 billion per year.  
25 I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 know you have all read and seen these statistics.

2 In fact, the Federal Register notice of  
3 this very event today cited two of these three  
4 numbers. The problem is that all three of them are  
5 seriously flawed.

6 Let's start with the common belief that  
7 each year 300,000 U.S. deaths are attributable to  
8 excess weight. Here is the truth. The data  
9 linking  
10 overweight and death are limited, fragmented, and  
11 often ambiguous. Now, that's from an editorial  
12 published by the respected New England Journal of  
13 Medicine in January 1998 questioning the  
14 increasingly  
15 frantic rhetoric about obesity as a public health  
16 problem.

17 And speaking specifically about that  
18 300,000 number, the New England Journal continued,  
19 "That figure is by no means well-established." I  
20 am  
21 going to read that again. "That figure is by no  
22 means  
23 well-established. Not only is it derived from weak  
24 or  
25 incomplete data, but it is also called into

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 question  
2 by the methodologic difficulties of determining  
3 which  
4 of the many factors contribute to premature death."

5 It turns out that in order to allege  
6 that  
7 300,000 Americans die each year from obesity, you  
8 would have to claim that everyone who dies while  
9 overweight dies because they are overweight. It  
10 turns  
11 out that even car accident fatalities count toward  
12 that total if the victim's BMI is too high.

13 Secondly, many in government and the  
14 mass  
15 media have blindly accepted the claim that obesity  
16 costs Americans \$117 billion a year, believing,  
17 most  
18 of them, that that figure came directly from the  
19 Surgeon General. But it turns out that the Surgeon  
20 General's original source for this number was a  
21 study  
22 published in the March 1998 issue of the journal  
23 Obesity Research, one single study.

24 Now, this study has serious  
25 limitations.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 And the authors themselves admitted that. Of  
2 course,  
3 that's not the part of the study that usually hits  
4 the  
5 headlines of the New York Times.

6 Here's what they wrote, "We are still  
7 uncertain about the actual number of health  
8 utilization associated with overweight and  
9 obesity."

10 And they explained that "Height and weight are not  
11 included in many of the primary data sources." So  
12 how  
13 could they even know what obesity costs America per  
14 year?

15 Here is the most interesting part.  
16 This  
17 studies authors defined obesity incorrectly. So  
18 how  
19 do you get to 117 billion a year? You use the  
20 wrong  
21 definition. This is from their study, "The current  
22 estimate of the cost of obesity defines obesity as  
23 a  
24 BMI of greater than or equal to 29."

25 Well, obesity, as we heard the last

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 speaker say correctly, is actually defined as a BMI  
2 of  
3 greater than or equal to 30. Thus, the Obesity  
4 Research study, the sole plank on which the Surgeon  
5 General's claim of \$117 billion obesity cost is  
6 based,  
7 erroneously included the economic cost of  
8 individuals  
9 with BMIs between 29 and 30. And that is more than  
10 ten million Americans.

11 Now, finally, the authors of that study  
12 acknowledge that even if some of their data flaws  
13 were  
14 corrected, their methodology would still result in  
15 double or even triple counting of obesity-related  
16 costs.

17 Here is what they write, "Our model  
18 assumes that coronary heart disease , hypertension,  
19 and diabetes occur independently." They go on,  
20 "However, we know that there is some  
21 interdependence  
22 among these disease states, especially in obese  
23 patients." And they admit that "calculating the  
24 cost  
25 of obesity as it relates to these diseases

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 independently would inflate the cost estimates," so  
2 much for that number.

3           Lastly, are 61 percent of Americans  
4 really  
5 overweight or obese? Well, as you know, overweight  
6 and obesity are diagnosed by using the body mass  
7 index, which is, frankly, a very flawed standard.

8           According to the Centers for Disease  
9 Control and Prevention, "Overweight may or may not  
10 be  
11 due to increases in body fat." Now, this is  
12 currently  
13 on the CDC's Web site. This is the CDC's current  
14 position. "Overweight may or may not be due to  
15 increases in body fat. It may also be due to an  
16 increase in lean muscle. For example, professional  
17 athletes may be very lean and muscular, with very  
18 little body fat. Yet, they may weigh more than  
19 others  
20 of the same height." I'm not telling you anything  
21 you  
22 probably don't already know.

23           And again they go on to say, "While  
24 they  
25 may qualify as overweight due to their large muscle

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 mass, they are not necessarily over fat, regardless  
2 of  
3 their BMI."

4 The CDC also notes, again currently on  
5 their Web site, "Two people can have the same BMI  
6 but  
7 a different percent body fat. A bodybuilder with a  
8 large muscle mass and a low percent body fat may  
9 have  
10 the same BMI as a person who has more body fat  
11 because  
12 BMI is calculated using weight and height only."

13 Using the BMI standard, by the way, our  
14 very fit President Bush is overweight. And the  
15 incredibly fit governor-elect of California is  
16 obese.

17 It's also worth noting that the  
18 definition  
19 of overweight used by the U.S. government was  
20 arbitrarily changed in 1998 -- this isn't talked  
21 about  
22 very much -- following political pressure brought  
23 by  
24 the World Health Organization. The definition that  
25 we

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4122

www.nealrsgross.com

1 abandoned in 1998 had one specific virtue, which is  
2 that it distinguish between men and women,  
3 something  
4 that our current standard does not do or does not  
5 even  
6 attempt to do.

7           The 1998 redefinition of overweight  
8 reclassified 39 million Americans as overweight.  
9 They  
10 literally went to sleep one night at a  
11 government-approved weight and woke up the next day  
12 overweight without gaining an ounce.

13           That group of Americans, by the way,  
14 presently includes overweight movie stars like Will  
15 Smith, Brad Pitt. It also includes Michael Jordan  
16 and  
17 Cal Ripkin, Jr. at the height of their athletic  
18 prowess. And Barry Bonds, by the way, the slugger,  
19 is  
20 obese. I hate to tell you he's obese.

21           So how does this all affect what the  
22 FDA  
23 should do going forward? First, we at the Center  
24 for  
25 Consumer Freedom caution the FDA against using that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com



1 \$117 billion figure in any way or relying on the  
2 300,000 death figure in its literature.

3 Secondly, we suggest that any mention  
4 of  
5 the notion of a 61 percent obese or overweight U.S.  
6 population should include a prominent disclaimer  
7 noting that the body mass index standard is  
8 imperfect,  
9 at best.

10 The last thing I have to say is look  
11 out  
12 for the hidden agendas because they are around  
13 every  
14 corner.

15 Thank you very much for the  
16 opportunity.

17 Good afternoon.

18 (Applause.)

19 VICE CHAIRMAN LEVITT: Thank you.

20 Our next speaker is Richard Elder,  
21 Senior  
22 Director, International Food Information Council  
23 Foundation.

24 MR. ELDER: Thank you.

25 Good afternoon. My name is Dick Elder.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1 I am the Senior Director at the International Food  
2 Information Council. And I, too, like the other  
3 speakers, would like to thank the Food and Drug  
4 Administration for convening this public session  
5 and  
6 providing us an opportunity to make our comments.

7 The International Food Information  
8 Council  
9 and the International Food Information Council  
10 Foundation is a nonprofit organization whose  
11 mission  
12 is to communicate science-based information on food  
13 safety and nutrition issues to the health  
14 professionals, media, educators, and government  
15 officials, who ultimately communicate this  
16 information  
17 on to the general public.

18 We are primarily supported by the  
19 broad-based food, beverage, and agriculture  
20 industries. And as a 501(c)(3), we do not lobby.  
21 We  
22 do not represent any particular product or  
23 industry.

24 Much of the work we do is in  
25 partnership

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 with a wide range of stakeholder groups in both the  
2 public, the not-for-profit, and the private  
3 sectors.

4 Some examples that I think are relevant for the  
5 discussion here today are that we have participated  
6 in  
7 the Dietary Guidelines Alliance -- and I'll come  
8 back  
9 and mention some output of that in a minute. We  
10 also  
11 are a partner in ACTIVATE, which is a childhood  
12 overweight prevention initiative. That is a unique  
13 kind of public-private partnership. We have also  
14 been  
15 actively involved in the partnership for healthy  
16 weight management.

17 Today we will address two of the six  
18 questions that have been posed by the committee.  
19 We  
20 will address them in the following way. We believe  
21 that rational, effective public efforts to prevent  
22 overweight and obesity and actions that would make  
23 a  
24 significant difference at some point are going to  
25 involve communicating with the general public. And

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 so  
2 our comments today will be directed on the focus of  
3 designing effective communications to reach these  
4 audiences.

5 First, it's important to craft messages  
6 that connect with consumers. If the communication  
7 that is contemplated here is intended to go beyond  
8 simple disclosure and to move in the direction of  
9 persuasion or encouraging people to modify or  
10 change  
11 their behavior, then it's important to connect  
12 these  
13 messages in a way, to construct these messages in a  
14 way that really connects with consumers.

15 For this to happen, in our experience,  
16 some form of consumer research is needed to  
17 understand  
18 how consumers think and feel about such a  
19 complicated  
20 issue as overweight, physical activity, and health.

21 For example, in a series of focus group  
22 interviews we recently conducted with adults, to  
23 better understand the perceived barriers to  
24 adopting  
25 healthy lifestyle habits, we found that consumers

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1 feel  
2 the demands of their everyday lives are  
3 overwhelming.

4 And, as a result, they're very aware that they make  
5 trade-offs away from healthy eating and regular  
6 physical activity on a daily basis.

7           And I think, to paraphrase them, I  
8 would  
9 say they would say something like, you know, we  
10 know  
11 what we should be doing. We just don't know how to  
12 manage our daily lives in a way so that we do it.  
13 So  
14 it's important to get a feel for where the  
15 consumers  
16 are in their lives as we move forward.

17           Second, to end up with messages that  
18 connect, it's important to define the target  
19 audience  
20 to be reached. Over the past three years in focus  
21 group research that we have conducted on overweight  
22 and obesity, we learned that in order to connect  
23 with  
24 tweens, for example, one target audience, which are  
25 kids 9 to 12, information needs to be presented in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 a  
2 way that is perceived by them as fun, boring -- not  
3 boring, -- excuse me -- and cool. If we're not  
4 careful, they will perceive it as boring.

5 In fact, what we found was commonly  
6 used  
7 terms like "fitness," "nutrition," "healthy  
8 eating,"  
9 and "physical activity" simply do not connect with  
10 kids in this age group. These ideas are boring  
11 and,  
12 probably more importantly for us, not motivating.

13 Over the past three years, when we  
14 talked  
15 to parents, we found that they didn't even perceive  
16 weight as a potential health issue. So where are  
17 they  
18 in their lives? They don't see this as a potential  
19 health issue right now.

20 And even if they did, they felt they  
21 didn't have the necessary communications skills to  
22 know how to talk to their kids about it, again, not  
23 necessarily information, but what are the skills,  
24 how  
25 do I conduct a conversation, and how do they do

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 this.

2 And they also know that they're not the  
3 best role models. So it's not exactly a strong,  
4 solid  
5 platform from which to start this dialogue with  
6 kids.

7 So the findings from these first two,  
8 the  
9 tweens and the parents, from this research was  
10 published in the June 2003 edition of the Journal  
11 of  
12 the American Dietetic Association. And you can  
13 find  
14 more on that there.

15 Now, new research that we currently  
16 have  
17 underway with adults, we hear very clearly back  
18 from  
19 consumers that lifestyle demands, rather than a  
20 lack  
21 of information about proper nutrition and physical  
22 activity, is really the principal perceived  
23 barrier.

24 Now, we're still in process with this  
25 research. We need to take more time to see how

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 this  
2 comes out. We still have some more phases to go.  
3 But  
4 that is some important learning, and I think it is  
5 something we should all pause and think about as we  
6 move forward.

7           Finally, once target audiences are  
8 defined, messages should be tested. Effective  
9 messages generally evolve over a series of  
10 iterations  
11 that involve testing, refinement, redrafting,  
12 testing,  
13 redrafting, refinement. And eventually you end up  
14 with a message that works.

15           In the research that is currently in  
16 process, we tested a number of potential messages  
17 that  
18 might motivate consumers to adopt healthy lifestyle  
19 behaviors. Here are two of the messages that we  
20 tested. And, as you can see, consumers responded  
21 positively to one and negatively to the other. I'm  
22 just going to take a minute to read through what we  
23 call the small steps concept and the message that  
24 came  
25 out of that.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1                   Though it's though, go ahead and take  
2 the  
3 first step toward a healthier lifestyle. Before  
4 you  
5 know it, your steps will add up and you're well on  
6 your way to reaching your goals.

7                   In general, consumers like that. Of  
8 the  
9 concepts we tested -- and we tested more than two  
10 --  
11 this was the one that they liked the best. They  
12 felt  
13 good about it. We're still learning why they felt  
14 good about it.

15                   The second concept was balance  
16 calories.  
17 And we've heard a lot about that today. The  
18 message  
19 was to maintain your weight, balance the number of  
20 calories you eat, with the number of calories you  
21 burn  
22 off.

23                   I've got to tell you this was the  
24 loser.  
25 This was at the bottom of the barrel. And, as I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4122

www.nealr.com

1 say,  
2 we're still in the process of learning that. When  
3 we  
4 get this research published, we will be more than  
5 happy to share all of this.

6 In general, consumers said, "I already  
7 know that. I don't find this very motivating.  
8 It's  
9 a no-brainer." They don't have time to count up  
10 all  
11 of their calories every day. That's their voice,  
12 where they're coming from on this.

13 Now, it's interesting that the small  
14 steps  
15 concept that we tested is very similar to a message  
16 that was tested a number of years ago and used in a  
17 program published by the Dietary Guidelines  
18 Alliance  
19 called It's All About You. You can see this  
20 concept  
21 is very similar. The message is be realistic.  
22 Make  
23 small changes over time in what you eat and the  
24 level  
25 of activity you do. And, after all, small changes

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 work better than giant leaps, so two very similar  
2 concepts tested about four or five years apart.  
3 This  
4 one I'm sure has been through testing and that's  
5 why  
6 it was used in this program.

7 So I think it's helpful to look and see  
8 what already exists and to see how it might be  
9 connected or improved to work together with the new  
10 focus for these messages now.

11 So, in summary, our experience is that  
12 working in partnerships can be very effective,  
13 whether  
14 they are existing partnerships or new partnerships  
15 that are formed around this issue, involve the  
16 consumer, do some sort of consumer research, hear  
17 the  
18 voice of the consumer, and let that guide our  
19 communication, target our messages.

20 Not all consumers think and feel the  
21 same  
22 way about these issues. And it's important for us  
23 to  
24 acknowledge that and then make sure that our  
25 messages

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 connect with consumers. And the way to do that is  
2 to  
3 test them and revise them.

4 Thank you very much for this  
5 opportunity,  
6 and I appreciate it.

7 (Applause.)

8 CHAIRMAN CRAWFORD: Sorry. Could I ask  
9 you a couple of questions?

10 MR. ELDER: Yes, sir, certainly.

11 CHAIRMAN CRAWFORD: You seem to be able  
12 to  
13 -- and I applaud you for being able to do this --  
14 put  
15 together like a message for dealing with obesity.  
16 But  
17 would you also agree that some more like basic  
18 biomedical research needs to be done or do you  
19 think  
20 we've got enough to go forward with an FDA-type  
21 program at this point?

22 You won't be the last one to be asked  
23 that.

24 MR. ELDER: Would the audience like to  
25 help me answer that question?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

1 I guess the one thing the research we  
2 have  
3 done is shown that kids and parents and to a lesser  
4 extent many health professionals still don't  
5 perceive  
6 obesity as a health issue. So in that way, I think  
7 the answer is that maybe there is some work that  
8 needs  
9 to be done on that type of a message.

10 CHAIRMAN CRAWFORD: Thank you.

11 MR. ELDER: Okay.

12 VICE CHAIRMAN LEVITT: Let me post  
13 facto  
14 welcome Dr. Crawford back to the panel and welcome  
15 our  
16 next speaker, Dr. Neal Bernard, President of the  
17 Physicians Committee for Responsible Medicine.

18 DR. BERNARD: Thank you very much for  
19 this  
20 opportunity to speak to the panel today.

21 The most important research that weighs  
22 on  
23 this issue in my view is comparing different  
24 countries  
25 that have very different patterns of body weight

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 and  
2 understanding what they're doing differently that  
3 may  
4 lead to that.

5 In the United States, our diet is  
6 rather  
7 like the one I grew up with in Fargo, North Dakota,  
8 where I come from a long line of cattle ranchers.  
9 Roast beef was the center of my plate. A baked  
10 potato  
11 was on the side, a little bit of vegetables. So  
12 just  
13 about every day was roast beef, baked potatoes, and  
14 corn. For special occasions, it was roast beef,  
15 baked  
16 potatoes, and peas.

17 Well, in Japan, that's not the case.  
18 Their dietary staple is not meat. It's rice. They  
19 eat phenomenal amounts of rice and vegetables,  
20 relatively little meat; if you're Buddhist, maybe  
21 none  
22 at all. Dairy is not a traditional product there.  
23 And if you look at the rates of obesity in Japan,  
24 historically it's been extraordinarily low, less  
25 than

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 one percent up until about 1980, while in the  
2 United  
3 States, we are far higher than that, up to about 15  
4 percent.

5 Now, things, of course, have changed in  
6 both countries. We now have McDonald's in Japan.  
7 And, as William Costellia Premium always says,  
8 "When  
9 you see the golden arches, you're on the road to  
10 the  
11 Pearly Gates," maybe true. And we have those same  
12 challenges here.

13 So while obesity rates have soared up  
14 to  
15 about 30 percent, -- I'm speaking just of BMI over  
16 30  
17 -- about 30 percent in the U.S., in Japan, it's  
18 soared  
19 all the way up to about 2 percent of the  
20 population.

21 So the rice-based diet has been helping them.

22 If you look at the more moderate  
23 overweight, we still are far higher than Japan.  
24 Within Japan, these are figures that have shown the  
25 effects of trading a rice-based diet for a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 Westernized

2 diet.

3 Rice consumption is falling  
4 dramatically.

5 Fat intake has risen dramatically. And obesity is  
6 rising. Longevity is declining. In Asia, it was a  
7 grain-centered diet, obesity being rare. In the  
8 U.S.

9 prior to 1980, we already had a meat-based diet.  
10 Obesity was common.

11 Since 1980, what has happened, we kept  
12 the  
13 same basic diet. We've added lots more calories in  
14 the form of cheese, in particular -- we'll come  
15 back  
16 to that in a minute -- and also sugar.

17 We also don't use carbohydrates the way  
18 Asians do. There it's used as a staple. Here it's  
19 used as a vehicle. That baked potato comes out of  
20 the  
21 oven. We slather with butter, sour cream, cheese  
22 doodles, and Bac-O Bits. That's true of just  
23 anything  
24 that can come out of our toaster or our oven.

25 We put the idea that reversing that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1 trend  
2 might help with individuals who are already  
3 overweight. These data are pending publication. I  
4 want to share them with you now.

5 We brought in 59 overweight women,  
6 randomly assigned them to either a low-fat vegan  
7 diet,  
8 meaning a pure vegetarian diet, which was lots of  
9 vegetables, fruits, grains, and beans. We held  
10 exercise constant. And we collected our data at  
11 baseline and 14 weeks.

12 Our control diet followed the national  
13 cholesterol education program guidelines, chicken  
14 and  
15 fish, no more than six ounces per day, that sort of  
16 thing.

17 Just to walk you through a couple of  
18 highlights, the nutrient intake, the first set of  
19 blocks is protein. The first two stripes are the  
20 vegans. Their protein intake dropped, but it was  
21 still adequate. Protein intake for the controls  
22 dropped, too, but look at the second group there:  
23 the  
24 carbohydrates. The vegans were eating a lot more  
25 carbohydrate, but the control group was eating

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 somewhat less.

2 Fat intake, the third cluster, dropped  
3 for

4 the vegans. And it dropped as well for the  
5 controls.

6 Fiber intake increased, which is what you would  
7 expect. Fiber only comes from plants. So in the  
8 vegan group, it rose to about 30 grams per day.  
9 And  
10 it rose just marginally in the controls.

11 Now, why do we emphasize fiber?

12 Because

13 if we're looking for something to help us cut  
14 calories, all the warnings in the world don't do as  
15 well as adding more fiber to your diet. And I  
16 don't  
17 mean shaking it out of a jar. I mean, having it in  
18 beans and grains and vegetables and fruits.

19 This is from a meta-analysis that is  
20 very,

21 very handy. Every 14 grams of fiber in your daily  
22 diet cuts your energy intake by about 10 percent.

23 Your average American consumes 12 grams or 13 grams  
24 of

25 fiber per day. That's pathetic. Yogurt and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 chicken  
2 breasts don't have fiber in them, but that bean  
3 burrito or side of vegetables will.

4 So what happened? Both groups reduced  
5 their energy intake. Both groups reduced their fat  
6 intake. This is our vegans compared to our  
7 controls.

8 The carbohydrate in the vegan group went way, way  
9 up.

10 And it went down in the others. When we look at  
11 weight loss, the first two bars are body weight in  
12 kilograms, the change in body weight.

13 Translated into pounds, it was about a  
14 13-pound weight loss in the vegan group over 14  
15 weeks,  
16 about a pound per week, which is great, and about  
17 half  
18 of that in the other group. I won't bore you with  
19 the  
20 other findings here, but please contact me if you  
21 are  
22 interested in the other metabolic effects, which  
23 are  
24 similarly impressive.

25 What is really interesting is -- and we

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 have been talking about Type II diabetes -- insulin  
2 sensitivity improved quite significantly in our  
3 vegan  
4 group. We had three or four people who were  
5 diagnosable as having Type II diabetes unaware of  
6 it  
7 at the onset of the study. At the end of the  
8 study,  
9 none of them had a glucose that could make that  
10 diagnosis.

11                   Bad news for people who go from beef to  
12 chicken. The leanest beef that my family can raise  
13 is  
14 about 29 percent fat as a percentage of calories.  
15 For  
16 chicken, it's about 23 with the skin removed and  
17 all  
18 the dark meat thrown away; green, leafy vegetables,  
19 though, very low in fat; beans extremely low in  
20 fat;  
21 rice and potatoes, same story.

22                   Okay. There's no evidence, there's  
23 just  
24 no controversy that a plant-based diet is good for  
25 us.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 So why don't we eat that way? Let me offer a  
2 theory  
3 that I think does bear some research and some  
4 investigation. Why are we attracted to sugary  
5 foods?  
6 Why are we attracted to cheese?

7 The one group that my vegan group after  
8 14  
9 weeks, I said, "What do you really miss?" It  
10 wasn't  
11 ice cream or a glass of full milk. They missed  
12 cheese. They were waking up at 5:00 in the morning  
13 dreaming of cheese pizza.

14 What is that about? I think we have  
15 some  
16 ideas about that. What is it about me? You  
17 remember  
18 this article in the New York Times magazine trying  
19 to  
20 suggest that it's not that steak in butter that's  
21 making us fat. It's all that rice we're eating and  
22 all of those potatoes. Come back to that in a  
23 second.

24 A fascinating line of research uses  
25 this

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

1 drug. This is NARCAN, the lock zone. It's used in  
2 emergency rooms. A man is overdosed on heroin.  
3 His  
4 buddies drag him into the ER. You inject him with  
5 NARCAN. It stops heroin from working on the brain.  
6 He wakes up. You've saved his life.

7 If you give that same drug  
8 intravenously  
9 to a chocolate addict -- I don't mean a person who  
10 likes it; I mean a person bingeing -- the most  
11 amazing  
12 thing happens. They lose much of their interest in  
13 chocolate. This is not a treatment. This is a  
14 research tool.

15 What it demonstrates is that taste and  
16 mouth feel are fine, but what counts and what keeps  
17 you hooked and what drives you to the 7-11 at 9:00  
18 o'clock at night is something going on in the  
19 brain.

20 And that is chocolate triggers the release of  
21 opiate  
22 chemicals within the brain that cause a little  
23 anesthesia and a little bit of a feel good effect.  
24 And that's why we turn to it when we need that kind  
25 of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 effect. It's used like a drug.

2 The same has been shown in studies in  
3 Britain with cheese, with meat, with sugar,  
4 especially  
5 sugar-fat mixtures, but not for broccoli, apples,  
6 oranges, raspberries, or cherries, which is why  
7 nobody  
8 ever went out late at night to say, "I've got to  
9 get  
10 an orange. I need broccoli."

11 Forget portion size control. You don't  
12 have to write that on the broccoli package. Nobody  
13 ever overdid it. The only foods we overdo it on  
14 are  
15 the ones we are addicted to. Whether we recognize  
16 it  
17 or not, we should use that word, sugar, chocolate,  
18 cheese, meat, period, or anything that produces  
19 sugar,  
20 like white bread. That can do it, too, but not  
21 vegetables, not whole, high-fiber grains, not  
22 beans.  
23 Nobody ever had a bean binge. It didn't happen.

24 Okay. Another line of research that  
25 has

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 been fascinating, I turned to this because I  
2 wondered  
3 why is cheese so addicting. Some of you know what  
4 I'm  
5 talking about. Others say, "Cheese just smells to  
6 me  
7 like old socks." Well, those who go into the  
8 refrigerator and eat it straight out of the pack,  
9 the  
10 dairy protein casein, like all proteins, is this  
11 long  
12 string of beads. Each bead is an amino acid. But  
13 in  
14 your digestive tract, it does not break apart into  
15 amino acids. It breaks into strings called  
16 casomorphins. These are peptides 4, 5, 7 amino  
17 acids  
18 in length. And they have opiate activity.

19 Do any of you ever overdose on cheese a  
20 little bit and you find yourself constipated the  
21 next  
22 day, almost the very same effect that you had if  
23 you  
24 were in the hospital and you got codeine after a  
25 surgical procedure because you have a narcotic

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704



1 going  
2 down your digestive tract that came from the  
3 cheese?

4 The process of turning milk into cheese  
5 is  
6 the process of concentrating casein and fat and  
7 eliminating lactose whey protein in water. It's  
8 the  
9 purest form of the drug. It's dairy crack.  
10 Halfway  
11 kidding. Okay.

12 The other thing -- this is from JAMA  
13 earlier this year -- supersizing is real. Our soft  
14 drink consumption has gone through the roof. When  
15 I  
16 was a kid growing up in North Dakota, we had sodas  
17 every two or three months at a birthday. Today  
18 they  
19 are daily fare. And your smallest bottle you can  
20 find  
21 at the 7-11 is 20 ounces. It contains almost as  
22 much  
23 caffeine as a cup of coffee and 250 calories no kid  
24 needs.

25 Fruit drinks are bigger. Hamburgers

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

1 are  
2 bigger. Cheese is bigger. And cheese intake has  
3 doubled since 1975. Your average man or woman  
4 consumes in the course of a year, believe it or  
5 not,  
6 30 pounds of cheese. And I'm not eating any of it.  
7 So somebody is getting mine.

8                   So why is that? Well, part of that --  
9 and  
10 this is I think my most important message that I'd  
11 like to share with the panel -- is we will get  
12 nowhere  
13 with telling kids, "You have to exercise more. You  
14 need to exercise some self-restraint."

15                   If we don't as a country get our own  
16 federal government in synch, it's no good for the  
17 Department of Health and Human Services to promote  
18 health messages while the Department of Agriculture  
19 is  
20 promoting the very products we now know are a  
21 problem  
22 for us.

23                   We got this from the Freedom of  
24 Information Act. The USDA worked with Dairy  
25 Management, Inc. to figure out how we can trigger

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 food  
2 addiction essentially. These are not my slides.  
3 These are U.S. government slides through Dairy  
4 Management, Inc.

5 They identified a group of people they  
6 called cheese-cravers, people whose addictive  
7 behavior  
8 can be triggered. And they know their  
9 demographics.  
10 They are defined by not using cheese as an  
11 enhancement  
12 for your sandwich but by eating it straight, as a  
13 staple.

14 And that's the group that they wanted  
15 to  
16 trigger. They found you can do it not by working  
17 with  
18 Ma and Pa restaurants but by working with fast food  
19 chains that have feelers into every community.

20 So the government worked. They worked  
21 with Wendy's to release a product called the  
22 cheddar  
23 lovers' bacon cheeseburger. Don't get paranoid.  
24 This  
25 is just the way the government works. They worked

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrsgross.com

1 with Wendy's, paid them to release a product called  
2 the cheddar lovers' bacon cheeseburger, sold 2 and  
3 a  
4 quarter million pounds of cheese just on this  
5 sandwich, 380 tons of fat, 1.2 tons of pure  
6 cholesterol.

7           They worked with Subway, which had two  
8 sandwiches that didn't have cheese. So they fixed  
9 that. They worked with Pizza Hut to take an entire  
10 pound of cheese and put it on one person's pizza  
11 and  
12 worked with Burger King and Taco Bell to do what?  
13 To  
14 make sure that signage, menu arrangement, the  
15 little  
16 logo on the guy's hat at the cash register, and  
17 even  
18 the very question that they ask you as you go  
19 through  
20 the drive-through all has cheese in it, "Have a  
21 Monterey quesidillas today."

22           This was a government program, widely  
23 successful, and is the reason that your average  
24 person, including kids, are eating twice as much of  
25 this as before. Well, is cheese fattening? You

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1 bet,  
2 very high in calories, 70 percent fat as a  
3 percentage  
4 of calories, mostly saturated fat.

5 This was the last slide that was at  
6 this  
7 forum in the year 2000. It's a Gary Larson cartoon  
8 at  
9 a kids' playground. Can you see this, the spiders  
10 that wove in a Web to catch the kids? "If we pull  
11 this off, we'll eat like kings." Well, he did.  
12 And  
13 there's no sign of it stopping.

14 Okay. Let's try something different.  
15 How  
16 about people who naturally select a vegetarian  
17 diet.

18 Look at their BMIs. Well, they're skinnier.  
19 They're  
20 skinnier by far. If you look at male meat eaters  
21 versus non-meat eaters, the non-meat eaters have a  
22 lower BMI. If you look at the females, same story.

23 Does this mean we ought to recommend a  
24 vegetarian diet? I would argue we should. But if  
25 you're not to that point yet, we could stop saying

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1 the  
2 kids need to have meat or they need to have dairy  
3 in  
4 their diet. They don't. Kids who avoid it are  
5 healthier. They live longer. They're skinnier.  
6 They  
7 have 40 percent less cancer risk.

8 The same at Loma Linda. There was a  
9 nice  
10 study comparing vegans and non-vegetarians.  
11 There's  
12 quite a dramatic difference in the second line  
13 between  
14 their BMIs. You see this quite consistently,  
15 despite  
16 the fact that vegans eat lots of carbohydrate,  
17 which  
18 the new carbo phobia tells us we shouldn't.

19 Okay. Let me wrap up with some  
20 comments  
21 about something that, for some reason, we haven't  
22 talked about too much today. And that's the spread  
23 of  
24 carbo phobia across the U.S. It started July 7th  
25 last

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 year when the New York Times magazine released that  
2 big picture of a steak, saying, "The devil is the  
3 potato. Do the Atkins diet."

4 I just want to walk you through this  
5 briefly. The Atkins diet is very low in  
6 carbohydrate  
7 and high in protein and fat. People do lose weight  
8 on  
9 it in some occasions, but the reason they lose  
10 weight  
11 is only -- well, there are two reasons.

12 The first is that if you starve your  
13 body  
14 of carbohydrate, you lose all of the glycogen that  
15 is  
16 stored energy in your liver and in your muscle.  
17 Every  
18 pound of glycogen holds three pounds of water. So  
19 in  
20 the first two weeks of the Atkins diet, you are  
21 peeing  
22 out water, and you think it's incredible. "Scam"  
23 might be too harsh of a word, but it's a trick  
24 because  
25 all of that water weight is coming back later on.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 But  
2 it feels great and "I think I'm losing fat."  
3 You're  
4 not. You're losing water.

5 But you will lose fat if you follow the  
6 diet as prescribed provided and only provided you  
7 leave out so many foods that your calorie intake  
8 drops. So the diet says you can't eat any fruit  
9 and  
10 starchy vegetables, any legumes, any grains, any  
11 milk.

12 Leave all of that out, and you'll lose weight.  
13 That's  
14 true unless the meat calories or cheese calories  
15 compensate, in which case you get nowhere.

16 We have analyzed the Atkins recommended  
17 menus, and they're terrible. Fiber intake on the  
18 induction phase is 2 grams a day, maintenance 18  
19 grams  
20 a day, not anywhere near high enough; saturated fat  
21 intake very high, 38 grams, in the recommended  
22 menus;  
23 cholesterol through the roof.

24 Protein intake is very high. For some  
25 reason as this was marching on, we've forgotten

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com



1 that  
2 diets high in animal protein are hard on the  
3 kidneys  
4 and very hard on calcium balance.

5 By the way, some of you have heard the  
6 reports saying, "Well, I ate all of that meat and  
7 my  
8 cholesterol didn't go up or it actually fell."  
9 There  
10 are two competing issues. If your body shrinks by  
11 whatever means, a smaller body will have a lower  
12 cholesterol level than that same body when it was  
13 obese. Saturated fat and dietary cholesterol tend  
14 to  
15 raise cholesterol levels. So in Jerry Foster's  
16 study,  
17 while cholesterol levels rose on the Atkins diet,  
18 in  
19 Eric Westman's study at Duke, they seemed to drop.  
20 The net effect is probably about a trade-off until  
21 you  
22 stabilize, at which point the saturated fat and  
23 cholesterol are going to be a big problem for you.

24 This was a nice study from  
25 Kris-Etherton

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 just showing that it is the reduction in body  
2 weight  
3 that can really take the credit for any kind of  
4 cholesterol lowering with weight loss regimens.

5           There is no magic about doing the  
6 Atkins  
7 diet at all, quite the opposite. But what really  
8 worries us, did you see the data from the Harvard  
9 nurses' study earlier this year showing that the  
10 more  
11 animal protein you consume, the more you're going  
12 to  
13 lose kidney function?

14           Now, this is permanent. You don't get  
15 your kidneys back. And it's really in individuals  
16 who  
17 already have a mild decrease in kidney function.  
18 The  
19 problem is that's a lot of people, particularly  
20 people  
21 who are trying weight loss diets.

22           Individuals with diabetes, about 40  
23 percent already have mild loss of renal function;  
24 those with hypertension, same story. And the older  
25 you get, the more common it is. So if you follow

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 one  
2 of these high-protein diets, you're risking further  
3 and permanent loss of kidney function. Most  
4 studies  
5 of high-protein diets ignore this issue.

6 Calcium losses. This was a study done  
7 at  
8 the University of Texas in Dallas. They put  
9 individuals on a regular diet who are already  
10 losing  
11 calcium fairly aggressively. What I mean by losing  
12 calcium is it filters through the kidneys. It's  
13 lost  
14 in the urine. If you put them on a diet high in  
15 animal protein, exactly what you would expect is  
16 what  
17 you observe. Their calcium loss through the urine  
18 goes way, way up and even on the maintenance phase  
19 of  
20 the Atkins diet, the same story. But the studies  
21 of  
22 the high-protein diets don't track that.

23 Colon cancer. We have known for a long  
24 time that meat eaters have substantially more  
25 cancer

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4100

www.nealr.com

1 overall, colon cancer specifically. This is data  
2 from  
3 the Harvard School of Public Health in men and in  
4 women. Those who are eating meat, especially red  
5 meat, have substantially more colon cancer.

6 Is it from the carcinogens that form as  
7 you cook it? Perhaps. Is it due to cholesterol  
8 and  
9 bile salts? Perhaps. The bottom line is there is  
10 no  
11 reason for ever recommending a high-protein diet.  
12 All  
13 the high-protein diet studies have been too short  
14 to  
15 track colon cancer risk.

16 The new data on Alzheimer's disease  
17 show  
18 exactly the same thing. Those individuals with the  
19 high saturated fat intake have more Alzheimer's  
20 disease over time.

21 If you flip that around, there's an  
22 optimistic message here. We get away from the  
23 saturated fat and the animal fats. We have the  
24 opportunity to not only get slimmer, healthier, and  
25 open up our arteries again, if you know Ornish's

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 work,  
2 but perhaps reduce our risk of Alzheimer's.

3 So there are different approaches: the  
4 old-fashioned low-calorie diet, the Atkins diet, a  
5 vegan diet. They all stimulate weight loss at  
6 about  
7 the same trajectory and rate. And what determines  
8 how  
9 much weight you lose is how long you stay on the  
10 diet.

11 And our study had slightly better weight loss over  
12 time than Atkins.

13 What really counts, this is Ornish's  
14 study, where he tracked individuals put on a  
15 vegetarian diet to open up their arteries. They do  
16 great. But five years later, they had not regained  
17 the weight they lost. They came back some, but,  
18 unlike every other dieter whose weight is going up  
19 and  
20 up and up and up, they never got back to their  
21 baseline weight. And that is really our message.

22 Finally, let me just conclude with one  
23 thing. The dairy industry has kicked off a new  
24 program to try to say dairy products will promote  
25 weight loss. Be very cautious about something like

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 this. Their evidence is based on mouse studies and  
2 on  
3 randomized trials where they use low-calorie  
4 restricted diets and they're talking about how  
5 calcium  
6 may promote weight loss.

7                   The message they want you to take is  
8 that  
9 if I add dairy products to my diet, I'll lose  
10 weight.

11 It doesn't work that way. There are at least 12  
12 randomized clinical trials looking at this.

13 Individuals who add dairy products to their diet  
14 either have no effect on weight or gain weight.  
15 Why?

16 Because cheese is 70 percent fat, skim milk is  
17 about  
18 55 percent sugar, lactose sugar.

19                   So what we need is a diet based on what  
20 we  
21 call the new four food groups: grains, legumes,  
22 vegetables, and fruits. If we're not prepared to  
23 say,  
24 "Let's go to a vegetarian diet," at least we should  
25 make meat and dairy no more than optional.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   And if you'd like any further  
2 information  
3 on any of these or if you would like the references  
4 for the studies that I've presented, I'd be only  
5 too  
6 happy to share them with you.

7                   Thank you very much for your time and  
8 attention.

9                   (Applause.)

10                  CHAIRMAN CRAWFORD: Just a couple of  
11 clarifying points. Thank you for finishing on  
12 time.

13                  You mentioned that you are concerned  
14 about  
15 food addictions. And you talked about the  
16 chocolate  
17 phenomenon and so forth. But then at one point,  
18 you  
19 talked about cheeses going down your intestinal  
20 tract  
21 and referred to them as narcotics.

22                  DR. BERNARD: Right.

23                  CHAIRMAN CRAWFORD: But if they were  
24 narcotics, there would have to be some biochemical  
25 change that was identified, like a tigroid

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4122

www.nealrsgross.com

1 substance

2 or something like that.

3 DR. BERNARD: Yes. Great question.

4 Okay.

5 I'm sorry I cut this short. By the way, let me  
6 shamelessly recommend a book that I recently wrote  
7 that goes to all of these issues and talks to --

8 CHAIRMAN CRAWFORD: Is there a cost?

9 DR. BERNARD: Not for you.

10 (Laughter.)

11 DR. BERNARD: It's called "Breaking the  
12 Food Seduction." It came out from St. Martin's  
13 Press.

14 I walk through not only cheese and meat but also  
15 sugar

16 and chocolate because, let's face it, people have  
17 suspected there's an addictive component to these.  
18 And I just wanted to lay out what the heck it is.

19 But yes, with regard to dairy, the  
20 casomorphins are produced within the digestive  
21 tract.

22 If in a bioassay you look at them for opiate  
23 activity

24 -- and there are a variety of standardized  
25 activities,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com



1 they clearly have it, not as much as heroin or  
2 morphine, and they vary depending on which one it  
3 is.

4           The strongest of these has about  
5 one-tenth  
6 the opiate activity of pure morphine. I did not  
7 write  
8 this book or make this presentation today to  
9 suggest  
10 that we are ready to slam the door and call this  
11 research completed.

12           I wanted to open the door and say that  
13 we  
14 should collectively look at -- while we know the  
15 casomorphins are absorbed in an infant's blood,  
16 they  
17 go to the brain and some researchers feel that that  
18 opiate effect is responsible for the mother-infant  
19 bond, why babies get that goofy look on their faces  
20 after nursing and they fall off to sleep --

21           CHAIRMAN CRAWFORD:       You're talking  
22 about  
23 your babies?

24           (Laughter.)

25           DR. BERNARD:    But in adults, we don't

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 yet  
2 know the extent to which casomorphins are absorbed.  
3 And that's something that remains to be seen.

4 CHAIRMAN CRAWFORD: Thank you.

5 One other point, you talked about  
6 calcium  
7 absorption and compared legumes, et cetera, to milk  
8 and dairy products. Are you prepared to agree that  
9 absorption is better with a little fat, like in  
10 cheese, or do you think the absorption of calcium  
11 is  
12 the same, say, in spinach as it is in cheese?

13 DR. BERNARD: Okay. The most important  
14 point here is that absorption is less than half the  
15 issue. We have more osteoporosis in this country  
16 by  
17 far compared to countries that never consume dairy  
18 or  
19 very rarely do. And we have one of the highest  
20 calcium intakes of any part of the globe, and we've  
21 got lots of osteoporosis.

22 When you look at studies on dairy  
23 consumption and osteoporosis over time, you see  
24 virtually no protection at all. I'm talking about  
25 the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrsgross.com

1 Harvard data 18 years out, including most of the  
2 randomized clinical trials and others, show little  
3 or  
4 no effect. Those that do show an effect don't use  
5 dairy. They use calcium supplements because they  
6 don't have animal protein in them. They don't have  
7 sodium because those things increase the calcium  
8 loss.

9 But yes, there are many, many factors  
10 that  
11 do affect absorption. You're absolutely right.  
12 Spinach is a terribly example because it has a very  
13 poor absorption fraction. The other green, leafy  
14 vegetables, like broccoli, have quite a high  
15 absorption, slightly higher than dairy. They have  
16 somewhat less calcium than dairy, but over time a  
17 plant-based diet is associated with better calcium.

18 CHAIRMAN CRAWFORD: Any other  
19 questions?

20 (No response.)

21 CHAIRMAN CRAWFORD: Okay. Thank you  
22 very  
23 much.

24 DR. BERNARD: Thank you very much.

25 (Applause.)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   VICE CHAIRMAN LEVITT: Our next speaker  
2 is  
3 Dr. Michael Jacobson, Executive Director, Center  
4 for  
5 Science in the Public Interest.

6                   DR. JACOBSON: Good afternoon. Thank  
7 you  
8 very much for the opportunity to speak here. The  
9 CSPI  
10 is a nonprofit consumer advocacy organization  
11 that's  
12 advocated improved government policies and  
13 corporate  
14 practices to promote better health, especially with  
15 regard to nutrition and food safety. And, as one  
16 of  
17 the previous speakers so kindly noted, we're also  
18 called the food police because we're out there  
19 looking  
20 for problems.

21                   One of the most important and discussed  
22 health problems of our time is rising rates of  
23 overweight and obesity. I applaud the FDA and HHS  
24 for  
25 taking the initiative to explore ways in which the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1 FDA  
2 can use its authority to help prevent weight  
3 problems  
4 as well as other diet-related health problems.

5 I would like to offer a few thoughts in  
6 response to three of the agency's questions. I  
7 would  
8 first like to comment on the FDA's section  
9 question,  
10 which concerned nutrition research to reduce  
11 obesity  
12 in children.

13 Obviously the challenge is to get kids  
14 to  
15 eat more healthful foods and to get more exercise.

16 On  
17 the nutrition side, it is conventional wisdom that  
18 children should limit their consumption of  
19 expendable  
20 nutrition-poor foods, like soft drinks and candy,  
21 and  
22 consume more fruits, vegetables, low-fat dairy  
23 products, and whole grains. A healthier diet would  
24 not only have a higher level of nutrients but would  
25 emphasize foods that are more filling.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1                   At least one observational study by  
2 Ludwig  
3 and his colleagues associated higher soft drink  
4 consumption with weight gain in school children.  
5 Considering how much soda pop children, especially  
6 teenagers, consume, FDA should initiate large  
7 studies  
8 to explore that issue much further.

9                   As we just heard from the previous  
10 speaker, vegetarians tend to be leaner and  
11 healthier  
12 in many other regards than the average American.  
13 It  
14 would be worth exploring in detail whether kids who  
15 eat healthful, largely vegetarian diets have a  
16 lower  
17 risk of gaining excessive weight.

18                   Difficult as it might be, it would be  
19 worth conducting intervention studies that  
20 encourage  
21 kids to eat a vegetarian diet or a largely  
22 plant-based  
23 diet, like the Dash diet, to see if it protects  
24 against obesity.

25                   And, be it for kids, adults, or

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 families,  
2 HHS should invest heavily in community-wide mass  
3 media  
4 campaigns to promote more healthful diets.

5 CSPI's studies of using the mass media  
6 to  
7 move people from high-fat to low-fat milk were  
8 enormously successful. In less than two months, we  
9 as  
10 much as doubled the market share of skim and  
11 low-fat  
12 milk. Similar campaigns should be conducted to  
13 move  
14 people towards whole grains, to eat more fruits and  
15 vegetables, to eat fewer fried foods, and so on.

16 Let me skip question three and go on to  
17 the fourth question about using food labeling to  
18 encourage people to eat healthier diets. I would  
19 like  
20 to make several suggestions for how the FDA could  
21 improve food labeling to provide consumers with a  
22 greater understanding of the calorie content of  
23 foods  
24 and to encourage consumers to choose more healthful  
25 foods overall.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   Many products, like ice cream, potato  
2 chips, and breakfast cereals, are marketed in  
3 containers that contain multiple servings.  
4 Nutrition  
5 facts labels indicate the calorie content of the  
6 official single serving, but many people  
7 unwittingly  
8 eat several servings at a time and assume they have  
9 consumed only the calories in that one serving.

10                   The FDA should consider requiring  
11 labels  
12 to state not only the number of calories per  
13 serving  
14 but also the number of calories per package, per  
15 whole  
16 package, or in the case of very large packages, a  
17 fraction of the package.

18                   For instance, packages that contain one  
19 to  
20 five servings should list the total number of  
21 calories  
22 per package, packages that contain six to ten  
23 servings  
24 should list the calorie content per half package,  
25 and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com



1 so on, for even larger packages.

2                   Furthermore, the FDA should study  
3 whether  
4 listing the calorie content per serving and per  
5 package in larger, bolder type might encourage  
6 people  
7 to pay more attention to calories. And, as one  
8 person  
9 earlier mentioned, maybe we should have calories on  
10 the front of the package.

11                   Another serving size problem is that  
12 manufacturers of single serving foods are allowed  
13 to  
14 list nutrition information, either for the standard  
15 reference size, which is often quite small, or for  
16 the  
17 entire single serving package, which is what people  
18 typically consume.

19                   That gaping loophole has allowed a  
20 20-ounce soft drink to list calories for only 8  
21 ounces. Some packages list nutrients for only half  
22 a  
23 pot pie or half a package of Ramen soups. A chef  
24 salad that is clearly packaged as a single serving  
25 can

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 list calories for just one-third of the container.  
2 And single serving cups of salad dressing may list  
3 calories for only two-fifths of that little cup.

4 The FDA should propose new regulations  
5 to  
6 solve that problem. We cover this issue in our  
7 Nutrition Action newsletter. And I will leave a  
8 couple of articles here.

9 Second, special attention should be  
10 given  
11 to one particular food that is consumed in enormous  
12 quantities by many children. That is soft drinks.

13 Over the past several decades, the soft  
14 drink and restaurant industries have changed the  
15 dietary role of soda pop from an occasional treat  
16 to  
17 a standard drink.

18 Because of its importance in the diet  
19 and  
20 because of evidence that soft drinks add excess  
21 calories to the diet and dilute the nutrient  
22 density  
23 of the diet, the FDA should consider requiring that  
24 a  
25 special advisory be printed on soft drink

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

1 containers.

2 That statement, inside some special logo, might  
3 read,

4 "Parents: Drinking too much soda pop may lead to  
5 obesity and tooth decay. Limit your children's  
6 consumption."

7 Diet contributes not only to weight  
8 gain  
9 but also to tooth decay, osteoporosis,  
10 cardiovascular  
11 disease, and cancer. The FDA should help consumers  
12 choose foods not only on the basis of their calorie  
13 content but their overall nutrient content.

14 The nutrition facts label has been a  
15 boon  
16 to millions of people, but it would be useful if it  
17 were supplemented with simpler, more direct  
18 information. The FDA should make it a top priority  
19 to  
20 study ways to use the food label to help consumers  
21 choose the most healthful foods.

22 One approach that I would like to spend  
23 a  
24 couple of minutes on would be to allow the front  
25 labels of qualifying foods as well as retail

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 displays  
2 of fruits, vegetables, and other unpackaged foods  
3 to  
4 bear a special symbol signifying that that food is  
5 quite healthful. The program I envision would be  
6 entirely voluntary and free to companies.

7           Such labels would enable people, even  
8 those people largely ignorant about nutrition, to  
9 easily identify healthful foods, foods that might  
10 reduce their risk of obesity and other health  
11 problems.

12           The FDA would have to do two things to  
13 implement such a program. First, it would need to  
14 develop appropriate criteria, perhaps starting with  
15 its definition for "healthy"; then develop a symbol  
16 that could be used on labels and also in packaging  
17 in  
18 advertising.

19           The American Heart Association and  
20 similar  
21 groups abroad have developed criteria for foods  
22 that  
23 it considers heart-healthy. It licenses companies  
24 to  
25 print a special heart check symbol on labels of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 foods  
2 that meet its criteria. It's a good program, but  
3 because the program is fee-based and operated by a  
4 private entity, it has had limited use in the food  
5 industry.

6 A better example is the Swedish  
7 government's healthy food program. Sweden has  
8 developed criteria for about a dozen categories of  
9 foods. For instance, breads must be whole grain  
10 and  
11 at least 11 percent dietary fiber. Milk must have  
12 no  
13 more than one-half percent butter fat. The fat  
14 content of entire meals must not exceed -- these  
15 are  
16 packaged meals or meals in restaurants -- must not  
17 exceed 30 percent of the calories. The government  
18 allows the use of its official keyhole symbol on  
19 packages that meet the relevant criteria.

20 And this is an example of the seafood  
21 curry. I'm not sure you can see it back on the far  
22 seats, but there is a little keyhole symbol printed  
23 on  
24 the package.

25 While one could debate the specific

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 criteria that Sweden uses or the American Heart  
2 Association, the basic concept is sound. According  
3 to  
4 the Swedish government, most foods that meet the  
5 criteria bear this keyhole symbol. I think this  
6 could  
7 be extremely useful in the United States to draw  
8 people to the most healthful foods.

9 In addition to the carrot of a good  
10 food  
11 symbol, there could be a stick to help consumers  
12 avoid  
13 less healthful foods. One of the single most  
14 important nutrition concerns is saturated fat and  
15 trans fat because of their role in promoting heart  
16 disease. Food labels could better highlight foods  
17 high in saturated and trans fats.

18 The FDA has said that foods that  
19 contain  
20 four grams or more per serving are high in  
21 saturated  
22 fat. The FDA could require such foods containing  
23 more  
24 than four grams of saturated fat per serving to  
25 bear

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 a special symbol on the front of the package. USDA  
2 could do the same for the foods under its  
3 jurisdiction

4 along with an accompanying statement like "High in  
5 saturated fat. Eat smaller portions and less  
6 often."

7 And the nutrition label, where there is space,  
8 could  
9 also use the word "high" next to "saturated fat" on  
10 those foods.

11 Let me turn now to question six that  
12 has  
13 to do with the FDA asked, what are the most  
14 important  
15 things that the agency could do to address the  
16 problem  
17 of overweight and obesity? In addition to the  
18 healthful food symbol to draw people to the most  
19 healthful foods, the FDA needs to recognize that  
20 Americans are getting an ever greater portion of  
21 their  
22 foods at restaurants, cafeterias, and vending  
23 machines, locations where there is rarely any  
24 nutrition information.

25 Meanwhile, the Department of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 Agriculture  
2 and other researchers have found that we eat less  
3 nutritious meals when we eat outside of the home.  
4 We  
5 eat more calories and get fewer nutrients.

6 But because of industry lobbying back  
7 in  
8 1990, the Nutrition Labeling and Education Act does  
9 not require restaurants to provide patrons with any  
10 nutrition information except in very special  
11 circumstances.

12 New laws are needed to require chain  
13 restaurants to post calories on menu boards and  
14 where  
15 there is more space to list the calories, saturated  
16 plus trans fat, and sodium on printed menus.

17 It would be extremely useful to  
18 consumers  
19 to see right on the menu board or menu that a  
20 medium  
21 soft drink had 200 calories, a large one 400, and a  
22 huge one 600 or that a regular order of fries had  
23 300  
24 calories and the huge version 600 calories. Such  
25 information might be the single most effective way

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4122

www.nealr.com



1 to  
2 encourage calorie-conscious consumers to choose  
3 smaller serving sizes outside the home.

4 While some restaurants provide  
5 nutrition  
6 posters, Web site information, or brochures, those  
7 can  
8 be hard to find and read and are really a waste of  
9 money. The only real way to help consumers would be  
10 to  
11 list calories and other information right at the  
12 point  
13 of purchase on menu boards and menus.

14 A few chains are actually doing that,  
15 at  
16 least for their healthier items. For instance,  
17 Baja  
18 Fresh, a chain of more than 200 restaurants, lists  
19 calories, fat, sodium, and fiber on its special  
20 lighten up menu over here under each of the six  
21 items.  
22 Olive Garden does the same for its garden fare  
23 items.

24 Currently several states and the  
25 District

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 of Columbia are considering legislation that would  
2 require that nutrition information on menus and  
3 menu  
4 boards. And I expect that a bill soon will be  
5 introduced in the House of Representatives.

6 I urge the FDA and the Department of  
7 Health and Human Services not to support silly tray  
8 liners or Web site information but to strongly  
9 support  
10 those state and federal bills that give consumers  
11 key  
12 information, especially about calories, right when  
13 they are deciding what to buy.

14 Thank you very much.

15 (Applause.)

16 CHAIRMAN CRAWFORD: Dr. Jacobson, if I  
17 could? Thank you for a rich presentation.

18 If I could go back to that part, that  
19 area  
20 where you were talking about serving sizes and  
21 changes  
22 in the labeling, are you proposing that if it's,  
23 say,  
24 a 24-ounce container of something and the nutrition  
25 facts panel relates to like an 8-ounce serving

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 size,  
2 that you change it to show whatever the size of the  
3 container is, that the total amount of nutrients in  
4 that container be listed on the label or are you  
5 presuming that or recommending that both would be  
6 done; that is, a regular serving size plus the  
7 whole  
8 container?

9 DR. JACOBSON: That's right. That's  
10 right. Both would be done. I mean, there are a  
11 huge  
12 number of products out there. So for a five-pound  
13 bag  
14 of flour, I don't think it would make sense to list  
15 the total calories per container. So it may not  
16 apply  
17 to every food.

18 CHAIRMAN CRAWFORD: But let's say the  
19 container were three times the serving size.

20 DR. JACOBSON: That's right.

21 CHAIRMAN CRAWFORD: That's what you're

22 --

23 DR. JACOBSON: That's right. And I was  
24 thinking if it's up to five servings per container.

25 CHAIRMAN CRAWFORD: How much good do

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4100

www.nealr.com

1 you

2 think that would do?

3 DR. JACOBSON: I think any of the  
4 things  
5 we're talking about would make a little dent in  
6 obesity, not a huge amount. I think the most  
7 important thing, the biggest impact would be at  
8 restaurants to give people that little bit of  
9 information before they have bought the foods and a  
10 healthy food symbol to attract people to the most  
11 healthful foods.

12 And then I thought the previous speaker  
13 made a compelling presentation in many regards.  
14 I'm  
15 not sure that's within FDA's jurisdiction to do  
16 anything on it, but HHS I think certainly should  
17 look  
18 at people who are eating vegetarian diets. They  
19 are  
20 healthy. They live longer than the rest of us.

21 And HHS needs to consider and U.S.  
22 Department of Agriculture needs to consider whether  
23 it's going to be candid with the American public on  
24 what are the best diets to eat.

25 It's a lot easier to promote one

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 overall  
2 healthful diet -- I'm not saying you have to be  
3 vegetarian but moving in that direction -- than to  
4 tell people, "On breakfast cereals, do this. On  
5 ice  
6 cream, do that. On yogurt, do this. And pay  
7 attention to 100 different things."

8           If you count up the numbers on the  
9 nutrition facts label, a label, of course, which  
10 CSPI  
11 strongly advocated, there are probably three dozen  
12 numbers on a single label. It's confusing. We  
13 need  
14 simpler ways of encouraging people to eat a  
15 healthier  
16 diet for the sake of preventing obesity but also  
17 heart  
18 disease, cancer, and a whole lot of other  
19 diet-related  
20 problems.

21           CHAIRMAN CRAWFORD:       So you are  
22 advocating  
23 a comprehensive re-look at the label format, and  
24 all  
25 that sort of thing?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 DR. JACOBSON: Well, I don't know,  
2 especially in certain regards. But I think there  
3 may  
4 be tradeoffs of saying, "Let's add this but get rid  
5 of  
6 that."

7 CHAIRMAN CRAWFORD: And one more thing.  
8 What do you have against tray liners?

9 DR. JACOBSON: They're worthless.  
10 They're  
11 silly. They have no effect.

12 (Laughter.)

13 DR. JACOBSON: And these are --

14 CHAIRMAN CRAWFORD: What makes them  
15 silly?

16 I mean, are they more silly than others?

17 DR. JACOBSON: Well, they are temporary  
18 little things that may inform a few people, but  
19 then  
20 it's gone. You know, it's like telling the package  
21 food industry, "For three months, put nutrition  
22 information in a brochure that's handed to somebody  
23 at  
24 the checkout counter or even printed on the label."  
25 And then three months later, it's gone.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1                   And with the fast food industry, when  
2           the  
3           pressure is off and now that that lawsuit in New  
4           York  
5           has been dismissed, deep sigh of relief, "We don't  
6           have to do anything."

7                   The Congress looked at nutrition  
8           labeling  
9           15 years ago. And it didn't say, "Let's have a  
10          book  
11          at the end of every aisle in the supermarket with  
12          nutrition information so people could look that  
13          up."

14                   Congress said, "Look, somebody is  
15          checking  
16          out a box of cereal. Tell them what is in it right  
17          there. Then they can decide to buy it or not."  
18          And  
19          we need something similar or analogous for  
20          restaurants  
21          or at least chain restaurants. We're not saying  
22          every  
23          Mom and Pop has to do any nutritional analysis of  
24          every food. Standard items.

25                   It up there would say, "Big Mac, 590

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 calories, \$2.19." Right below it, it would say,  
2 "Regular hamburger, 150 calories, 99 cents." Give  
3 people that one bit of information.

4 And the reason the National Restaurant  
5 Association and the fast food companies are  
6 fighting  
7 it so much, fighting such proposals is they know it  
8 would have an impact. People would buy smaller  
9 portions.

10 CHAIRMAN CRAWFORD: Thank you very  
11 much.

12 DR. JACOBSON: Thank you.

13 (Applause.)

14 VICE CHAIRMAN LEVITT: Our next speaker

15 --

16 you will greet her because after her, we will take  
17 a  
18 break -- is Alison Kretser, Director of Scientific  
19 and  
20 Nutrition Policy, Grocery Manufacturers of America.

21 Did I do something wrong? No. Will  
22 speak  
23 now. I said you will greet her because upon  
24 completion. Sorry about that, Alison.

25 MS. KRETZER: Good afternoon. Thank

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com



1 you.

2 Obesity is an issue of paramount  
3 importance to the Grocery Manufacturers of America  
4 and  
5 its member companies. In 1999, the GMA board of  
6 directors identified it as a growing problem and  
7 one  
8 that was of special concern to the food and  
9 beverage  
10 industry.

11 At that time, GMA committed itself to  
12 helping to solve the obesity problem in America.  
13 This  
14 commitment led to the formation of two separate and  
15 distinct efforts to provide realistic, proactive  
16 solutions to help prevent and reduce obesity in  
17 America.

18 The first was the formation of the  
19 American Council for Fitness and Nutrition, of  
20 which  
21 GMA is a founding member. You will hear from Dr.  
22 Finn, the council's chair, in a few minutes.

23 The second was the formation of a GMA  
24 food  
25 and health strategy group made up of senior food

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 and  
2 beverage industry executives. The group's purpose  
3 is  
4 to provide industry leadership to promote  
5 science-based efforts that positively impact  
6 critical  
7 nutrition and public health issues, ensure the  
8 global  
9 food and beverage industry is a positive force and  
10 a  
11 valid and responsible partner in addressing the  
12 obesity issue, and to collect examples of best  
13 business practices, such as corporate wellness  
14 programs, and encourage companies to adopt them.

15 The group is also committed to working  
16 with the Department of Health and Human Services  
17 and  
18 the USDA as they revise the dietary guidelines and  
19 the  
20 food guide pyramid.

21 In a statement submitted to the Dietary  
22 Guidelines Advisory Committee, GMA outlined ten  
23 principles for developing effective and realistic  
24 nutrition and physical activity recommendations for  
25 Americans.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1           As a whole, the principles stressed the  
2 importance of eating a nutritionally balanced diet,  
3 engaging in regular physical activity, and the need  
4 for Americans to moderate their food intake to  
5 match  
6 their level of physical activity. These principles  
7 are relevant to GMA and the strategy groups' total  
8 commit to reduce and prevent obesity in America.

9           We believe these principles will help  
10 all  
11 Americans lead healthy and active lives by giving  
12 them  
13 information about nutrition and physical activity  
14 that  
15 is understandable and relevant to their daily  
16 lives.

17           Specific initiatives the industry is  
18 spearheading addressed product innovation, improved  
19 labeling, advertising, and working with all  
20 stakeholders in the obesity debate, most notably  
21 the  
22 FDA and all critical policy-makers.

23           GMA and the food industry as a whole  
24 acknowledge that we play an essential role in  
25 providing consumers with safe nutrition, enjoyable

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 and  
2 affordable food. We can make significant  
3 contributions by intensifying our efforts to  
4 provide  
5 a wide range of nutritious product choices and  
6 marketing these choices in a way that promotes  
7 healthy  
8 lifestyles.

9 To this point, we are committed to  
10 using  
11 our scientific knowledge and technological  
12 expertise  
13 to continue to research, develop, and offer a range  
14 of  
15 foods to meet many consumer needs, including  
16 nutrition, taste, convenience, and value.

17 While our companies have always been  
18 committed to providing American consumers with the  
19 highest quality products possible, we have seen a  
20 definite shift in consumer demand for more  
21 nutritious  
22 food choices.

23 Over the past 5 years, sales of a  
24 variety  
25 of so-called "better for you" foods averaged 18

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 percent gross, a definite sign that consumers are  
2 looking for new ways to meet their personal health  
3 and  
4 nutrition needs, including obesity. And our  
5 companies  
6 are responding by developing and introducing  
7 products  
8 and reformulating existing products to meet this  
9 demand.

10 Earlier this year, FDA announced two  
11 significant changes in food and beverage labeling,  
12 mandatory and quantitative labeling of trans fat,  
13 and  
14 voluntary qualified health claims. GMA is fully  
15 supportive of these initiatives as they have  
16 already  
17 begun to spur additional competition among food  
18 companies to develop more and better foods to meet  
19 consumer demand for nutritious foods and beverages.

20 GMA also supports additional efforts to  
21 improve nutrition labeling, including setting  
22 regulatory standards for low-carbohydrate nutrient  
23 content claims and conducting consumer research  
24 regarding consumers' perceptions of calories and  
25 serving sizes.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1                   In the case of trans fat, the GMA  
2 supports  
3 FDA's decision to require quantitative labeling of  
4 trans fat as a separate line within the nutrition  
5 facts box. We believe this regulation provides  
6 consumers with concise information about the  
7 content  
8 of trans fat in their foods and will allow them to  
9 make informed choices about which products to  
10 purchase  
11 based on their own preferences and health needs.

12                   GMA also encourages the FDA to work  
13 with  
14 researchers developing new varieties of oils that  
15 have  
16 healthier nutrition profiles. For example, GMA  
17 member  
18 companies are investing a great deal of time,  
19 resources, and research into finding alternative  
20 oils  
21 that do not contain trans fat.

22                   Manufacturers are working closely with  
23 ingredient suppliers to bring new technologies and  
24 new  
25 varieties of oils to the market. With the FDA's

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1 support for this type of research, the industry is  
2 confident that it can significantly reduce the  
3 amount  
4 of trans fat in the food supply.

5 GMA strongly supports FDA's pre-market  
6 notification system for proposed qualified health  
7 claims submitted by food companies and others. As  
8 long-time supporters of qualified health claims for  
9 foods, GMA firmly believes this system will allow  
10 the  
11 food industry to get the newest health information  
12 onto the food label and into the hands of  
13 consumers,  
14 empowering them to make in-store comparisons.

15 More importantly, the ability to use  
16 qualified health claims will provide food  
17 manufacturers with yet another incentive to develop  
18 and market new nutritious products. GMA does have  
19 serious concerns about consumer perception of how  
20 qualified health claims will be used.

21 There's a comment, myth perception in  
22 the  
23 media that the market will now be flooded with  
24 snake  
25 oils and that the food industry will pursue claims

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 with minimal scientific support, such as claims  
2 ranked  
3 as C or D by FDA. These beliefs are entirely  
4 inaccurate.

5 GMA's member companies have built their  
6 success upon consumer trust in the quality of their  
7 brands, a trust that our companies intend to  
8 maintain  
9 by pursuing only those claims that can be  
10 substantiated by a credible body of science-based  
11 research.

12 Examples of the types of claims GMA  
13 member  
14 companies may pursue include low-fat dairy foods  
15 may  
16 reduce the risk of hypertension and Omega 3 fatty  
17 acids may reduce the risk of heart disease.

18 GMA also fully supports and commends  
19 the  
20 FDA for their flexibility in accepting consumer  
21 research data submitted by the International Tree  
22 Nut  
23 Council that helped determine the actual wording of  
24 the first approved, qualified health claim.

25 GMA believes the FDA should use this as

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1 the model for developing future qualified health  
2 claims because consumer research can significantly  
3 inform the decision-making process. More  
4 importantly,  
5 consumer research can ensure that the most  
6 effective  
7 wording is used in a qualified health claim based  
8 on  
9 the FDA's reasonable person standard.

10 For years, our member companies have  
11 quietly reduced the level of calories and certain  
12 nutrients in the brand name products. This  
13 includes  
14 finding ways to make incremental continued  
15 reductions  
16 of sodium and fats in foods. In many cases, these  
17 reductions are not significant enough to warrant  
18 nutrient content claims, such as reduced sodium.

19 GMA believes it is important for FDA to  
20 consider ways to encourage companies to continue to  
21 make these incremental changes that when adopted  
22 broadly could have a significant impact on consumer  
23 health.

24 As FDA reviews the expected report from  
25 the Institute of Medicine on the Committee on Uses

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 of  
2 Dietary Reference Intakes, FDA should consider what  
3 incentives might be appropriate to spur continued  
4 industry efforts on this front, including revisions  
5 to  
6 nutrient content claim standards.

7 With the growing popularity of  
8 low-carbohydrate diets, the food industry is  
9 seeking  
10 ways to respond to consumer demand for foods that  
11 meet  
12 their dietary and weight loss goals. This means  
13 developing and promoting foods that are low in  
14 carbohydrates.

15 However, there are no government  
16 regulations defining what constitutes a low-carb  
17 claim  
18 for foods. Therefore, at the request of its  
19 members,  
20 GMA will submit to FDA a citizens' petition  
21 outlining  
22 our recommendation for the definition of a  
23 low-carbohydrate claim in early 2004. We'll see if  
24 we  
25 can beat your February deadline.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 GMA believes that this request is  
2 consistent with FDA's publicly stated mission of  
3 providing more and better nutritional information  
4 to  
5 consumers, a mission that GMA supports  
6 wholeheartedly.

7 We hope to work with the FDA to  
8 establish  
9 clear guidelines for the use of this nutrient  
10 content  
11 claim in order to provide consumers with consistent  
12 nutrition labeling information.

13 In the interim, GMA members, the makers  
14 of  
15 the world's most trusted brands are acting  
16 responsibly, as they always had, to determine what  
17 is  
18 the best way to meet consumer demand for  
19 low-carbohydrate foods and to provide foods that  
20 are  
21 safe and accurately labeled.

22 We are determined to maintain the  
23 hard-earned trust that we have earned from  
24 consumers  
25 around the world. We hope this FDA will address

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 this  
2 planned request as soon as possible.

3 As with other aspects of the label,  
4 calorie and serving size information within the  
5 nutrition facts panel must be conveyed to consumers  
6 in  
7 a way that is meaningful and relevant to how  
8 consumers  
9 live, work, and play.

10 In order to addressing emerging  
11 questions  
12 about consumer perceptions, other nutrition facts  
13 box  
14 calorie and serving sizes, GMA plans to commission  
15 consumer research that will explore several points,  
16 including how consumers use the food label to  
17 obtain  
18 calorie information, how to more effectively  
19 communicate calories in single serving packages,  
20 how  
21 calorie labeling might impact consumer behavior,  
22 how  
23 consumers react to and incorporate low and  
24 reduced-calorie products in their diets.

25 As GMA pursues this research, we

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 believe  
2 it would be extremely valuable to solicit FDA's  
3 input  
4 regarding our research protocol and hope that it  
5 might  
6 be possible that we can sit down. When completed,  
7 we  
8 also hope to work with FDA to use the findings to  
9 develop improved consumer education messages  
10 without  
11 the caloric value of food in a way that is  
12 applicable  
13 to consumers' daily lives.

14 Informing consumers about products and  
15 services available to them is essential if they are  
16 going to enjoy the benefits of the options that  
17 food  
18 companies provide. Educating consumers, especially  
19 parents and their children, how to meet their  
20 individual needs, taste, and preferences through  
21 the  
22 proper balance of activity and nutrition empowers  
23 consumers to maintain a healthy weight.

24 Advertising is an important means of  
25 communicating that information and a critical

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 element  
2 of the competition that drives innovation. Every  
3 advertiser knows that effective advertising depends  
4 on  
5 consumers' trust and respect. Accordingly, the  
6 members of GMA have a longstanding commitment to  
7 responsible advertising and marketing practices.

8           The food industry is continuing to  
9 ensure  
10 that its communications with consumers accurately  
11 portray the products, their intended uses, and the  
12 benefit they deliver. The industry is continuing  
13 to  
14 ensure that its advertising and marketing practices  
15 do  
16 not encourage overeating or inappropriate  
17 consumption  
18 of foods.

19           In addition, the industry is seeking  
20 ways  
21 to utilize its marketing capabilities to  
22 communicate  
23 healthy lifestyles' messages to consumers through  
24 multiple media from labeling to advertising to Web  
25 sites in many channels from retail customers to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 workplace environments.

2           The self-regulatory system managed by  
3 the  
4 National Advertising Review Council, NARC, deserves  
5 much of the credit for the truthful and responsible  
6 advertising that consumers seek today.

7           In the food sector, voluntary  
8 compliance  
9 with the decisions of the National Advertising  
10 Division and the Children's Advertising Review  
11 Unit,  
12 CARU, ensures that advertising meets the highest  
13 standards of truth and accuracy.

14           Moreover, adherence to CARU's  
15 self-regulatory guidelines of children's  
16 advertising  
17 has fostered advertising that promotes balanced  
18 diets  
19 and healthy lifestyles.

20           Despite these successes, the public is  
21 largely unaware of CARU's positive impact on  
22 children's advertising. The effectiveness of  
23 self-regulation derives from stakeholders'  
24 appreciation and its role of advertisers'  
25 participation in its procedures.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   To this end, GMA today sent a formal  
2 request to NARC asking that it embark on a campaign  
3 to  
4 raise visibility of its role to expand its  
5 monitoring  
6 of food and beverage advertising through the  
7 National  
8 Advertising Division and CARU.

9                   More specifically, we are encouraging  
10 CARU  
11 to publish a white paper explaining its principles,  
12 guidelines, and decisions applicable to food  
13 advertising. GMA has also urged all of its members  
14 to  
15 support CARU and to adhere to CARU's  
16 self-regulatory  
17 guidelines for children, children's advertising,  
18 several of which apply directly to diet, health,  
19 and  
20 nutrition.

21                   In terms of collective action with FDA,  
22 GMA firmly believes that this is necessary for all  
23 stakeholders to work with the FDA in a partnership  
24 to  
25 promote the administration's prevention messages in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1 the Healthier U.S. initiative.

2 We know the Department of Health and  
3 Human  
4 Services is launching public service announcements  
5 in  
6 collaboration with the Ad Council next year. And  
7 we  
8 would like the opportunity to work with you to  
9 leverage our collective reach through our products  
10 and  
11 distribution channels to get FDA's and HHS' obesity  
12 prevention message out to the general public.

13 To that point, GMA applauds HHS and the  
14 FDA efforts to provide consumers with better  
15 information about nutrition, physical activity, and  
16 the importance of striking the right balance  
17 between  
18 the two in order to live a healthy lifestyle.

19 We support the administration's efforts  
20 to  
21 get more and better information into the hands of  
22 consumers so they can make better choices for  
23 themselves.

24 In conclusion, the food and beverage  
25 industry is committed to helping arrest and reverse

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 the growth of obesity around the world. Achieving  
2 this goal will require multiple strategies, the  
3 integrated efforts of many sectors, and long-term  
4 resolve.

5 We are committed to doing our part.  
6 And  
7 we will support others in doing theirs. We look  
8 forward to our continued partnership with FDA and  
9 HHS  
10 in achieving our shared goal of combatting obesity  
11 in  
12 America.

13 Thank you.

14 (Applause.)

15 CHAIRMAN CRAWFORD: You made a brief  
16 comment about the food guide pyramid. In doing so,  
17 I  
18 take it that you feel that it should be modified or  
19 converted into a parallelogram or whatever. Would  
20 you  
21 elaborate a bit on that in terms of what its role  
22 has  
23 been in either preventing or reducing obesity?

24 MS. KRETZER: Well, I would just like  
25 to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 comment that GMA is participating in the process as  
2 this revision works its way through. And we will.

3 We  
4 plan to submit comments to USDA to their technical  
5 document. Those are due on Monday.

6 We're looking at the proposed revisions  
7 that USDA put out. And we have some serious  
8 reservations about some of their proposed changes.  
9 One of the things I will share with you is the fact  
10 we  
11 feel that we will never be able to address this  
12 problem, obesity, unless we collectively help  
13 Americans to not only look at the amount of food  
14 that  
15 they need.

16 We recognize that we are half of that  
17 equation, but until Americans understand how to  
18 look  
19 at the total equation, then it's going to be very,  
20 very difficult. And so we hope that USDA will  
21 begin  
22 to embody HHS and FDA as they go forward looking at  
23 a  
24 lifestyle that includes both physical activity and  
25 the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 foods we eat.

2 VICE CHAIRMAN LEVITT: Thank you.

3 As promised, we will in a moment take a  
4 15-minute break. By my clock, it is 10 minutes  
5 before  
6 3:00. And so if people could reconvene, we still  
7 have  
8 a number of speakers that deserve to be heard. So  
9 we  
10 will reconvene at 3:05 in this room. Thank you  
11 very  
12 much.

13 (Whereupon, the foregoing matter went  
14 off

15 the record at 2:52 p.m. and went back  
16 on

17 the record at 3:16 p.m.)

18 VICE CHAIRMAN LEVITT: If I could ask  
19 everyone to take their seats, we will be able to  
20 proceed to the final section of our public meeting  
21 today.

22 As we are about to announce our next  
23 speaker, I would like to remind everyone that we  
24 have  
25 opened the public docket and that we encourage you

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 following this meeting to submit comments in  
2 writing.

3 You may have further thoughts. People in the  
4 audience

5 who did not speak I'm sure will have views that you  
6 would like to submit. And we encourage you to do  
7 that

8 to our written docket.

9 Our next speaker is Mr. Andrew Briscoe,  
10 President of the Sugar Association.

11 MR. BRISCOE: Thank you, Mr. Levitt.

12 Before I begin my official comments, I  
13 might say that on a personal note, I do struggle  
14 with

15 the word "diet" myself as a person myself, whether  
16 it's vegan diet, whether it's Atkins diet, because  
17 I

18 think some of my associates in the audience can  
19 attest

20 to the fact that I'm about 80 pounds lighter, but  
21 it

22 doesn't have anything to do with a diet. In fact,  
23 I

24 implemented about 2 or 3 years ago the physical  
25 fitness component in my life, which is about 30

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 minutes of physical fitness a day. So from a  
2 personal  
3 note, I reiterate the importance of that.

4 I am Andrew Briscoe, President and CEO  
5 of  
6 the Sugar Association. The Sugar Association  
7 represents sugar cane growers and refiners and  
8 sugar  
9 beet growers and processors in the United States.  
10 We  
11 would like to offer the following comments for  
12 FDA's  
13 consideration as you contemplate what action you  
14 can  
15 take to educate and assist the public in their  
16 quest  
17 for good health and well-being.

18 First and foremost, I would like to  
19 assure  
20 you that no food company or industry represented in  
21 this room wants anyone to be obese. That said, the  
22 Sugar Association has called for more involvement  
23 by  
24 all stakeholders, including representation from the  
25 food industry, to solve the battle against obesity.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 And that is why we are here today to testify. We  
2 want  
3 to be engaged in realistic, science-proven, and  
4 achievable results.

5 In the interest of time, we chose to  
6 focus  
7 on one of the six questions to provide input today.  
8 Question four specifically states, are there  
9 changes  
10 needed to food labeling that could result in the  
11 development of healthier, lower-calorie foods by  
12 industry and the selection of healthier,  
13 lower-calorie  
14 foods by consumers?

15 To respond to that, I would like to  
16 address the question of whether changes to the food  
17 label would result in the development of  
18 lower-calorie  
19 foods by the food industry by proposing the simple  
20 fact the American people are already blessed with  
21 an  
22 abundant supply of healthy foods, which enables  
23 them  
24 to enjoy nutrient-adequate diets that are the envy  
25 of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 the world.

2 We would like to assert that America's  
3 current dietary problems, including overweight and  
4 obesity, are not the result of lack of healthy,  
5 low-calorie diets but, instead, the results of  
6 individual choice and, frankly, we consume too much  
7 food.

8 The Sugar Association does not believe  
9 further development of so-called healthy,  
10 low-calorie  
11 foods will solve the national problem and, in fact,  
12 would be or could be counterproductive.

13 A perfect paradigm is the request for  
14 the  
15 development of low-fat food products in the '90s.  
16 The  
17 food industry was very responsive to the government  
18 and nutrition community's call for the development  
19 of  
20 low-fat versions of many foods.

21 Foods, whether low in fat or low in  
22 carbohydrate, must contain ingredients that mimic  
23 the  
24 functional properties of the original ingredients  
25 and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com



1 provide similar texture and consistency as well as  
2 good taste in order to be eaten.

3 A survey of many popular food items by  
4 Tufts University reported on in two recent articles  
5 in  
6 their newsletter titled "Low-Carb Craze or Low-Carb  
7 Crazy." And the second article was titled,  
8 "Sugar-Free Shortcomings." Both of them illustrate  
9 that low-carb or sugar-free versions were almost  
10 identical in calories as their full-carb or  
11 sugar-containing counterparts.

12 This should send up red flags from the  
13 lessons learned in the low-fat craze. As with  
14 low-fat, the current emphasis on cutting carbs once  
15 again is missing the calorie message and it gives  
16 us  
17 the psychological message that it's okay to eat  
18 more.

19 Over the past several decades, foods  
20 once  
21 considered staples of the American diet such as  
22 eggs,  
23 milk, and butter have come under attack. Now,  
24 rice,  
25 potatoes, sugars are all being labeled as potential

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 sources of health problems. We would like to  
2 suggest  
3 that to encourage the development of new foods or  
4 food  
5 ingredients to replace proven foods and ingredients  
6 is  
7 not without potential long-term health  
8 consequences.

9 We offer the trans fat example and also decreased  
10 calcium intake as examples.

11 To continue to move away from our  
12 natural  
13 food sources may have implications for metabolism,  
14 satiety, and taste preferences. The evidence is  
15 overwhelming that simply restricting one food item  
16 ingredient or macronutrient does not work.

17 It is also a fact that many so-called  
18 healthy foods are leading to weight gain simply  
19 because they are being consumed in portions that  
20 are  
21 in excess of what individuals need to maintain a  
22 healthy weight.

23 A nationwide educational effort by all  
24 stakeholders to assist the American public in  
25 understanding what is the proper portion size,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1       whether  
2       they are eating fruits, vegetables, dairy, grain,  
3       fast  
4       food, or dessert, would be a better use of current  
5       resources than another cycle of food development  
6       and  
7       remaking of the food label.

8                       The diets of the American public are  
9       very  
10       diverse. And so is the diversity of the opinion of  
11       the academic and nutrition community as to what  
12       foods  
13       should be considered as part of a healthy diet.

14                      We think all will agree on one thing.  
15       The  
16       health of the American public is improved  
17       considerably  
18       if the people eat less and increase their physical  
19       activity.

20                      As President of the Sugar Association,  
21       I  
22       must say a few words about sugar obviously. One of  
23       the main arguments for changing the food label to  
24       include the so-called added sugars is the assertion  
25       that added sugars' intake is a causative factor for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 obesity.

2 This is not substantiated by the  
3 science.

4 In fact, every major review of the scientific  
5 literature exonerates sugar's intake from any  
6 involvement in any disease, including obesity.

7 The most recent is a three-year study  
8 by  
9 the National Academy of Sciences' comprehensive  
10 review  
11 of scientific literature involving 279 references,  
12 which concluded, "Based on the data available on  
13 dental caries, behavior, cancer, risk of obesity,  
14 and  
15 risk of hyperlipidemia, there is insufficient  
16 evidence  
17 to set an upper limit for total or added sugars."  
18 It  
19 goes on to state, "There is no clear and consistent  
20 association between increased intakes of added  
21 sugars  
22 and BMI."

23 Continued emphasis on added sugars  
24 within  
25 the dietary guidelines, the food guide pyramid, or

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 any  
2 food label in the absence of valid scientifically  
3 verifiable health implications will only continue  
4 to  
5 obscure the real issue. If one consumes more  
6 calories  
7 than one burns, no matter what the source, weight  
8 gain  
9 is inevitable.

10 The Sugar Association believes the  
11 American consumers will be better served by  
12 nutrition  
13 advice that can withstand the scrutiny of  
14 collective  
15 scientific evidence on the food label as well as in  
16 nutrition policy.

17 Those are our comments today. And we  
18 will  
19 certainly expand upon them in our written comments  
20 submitted to you later. We certainly appreciate  
21 the  
22 opportunity.

23 CHAIRMAN CRAWFORD: Let me ask you  
24 about  
25 your exercise program.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 MR. BRISCOE: Yes, sir, by all means.

2 CHAIRMAN CRAWFORD: It's like a daily  
3 kind  
4 of thing, and is it --

5 MR. BRISCOE: Every day.

6 CHAIRMAN CRAWFORD: -- one of these  
7 that's  
8 syndicated or something like that or --

9 MR. BRISCOE: You know, of course, it's  
10 against the inside the Beltway mentality, but it's  
11 a  
12 simple approach. You dedicate 30 minutes a day. I  
13 alternate. I run every other day. And then I go  
14 and  
15 work out and lift weights every other day.

16 But I guess I would ask the audience  
17 here.  
18 How many of you worked out before you came to this  
19 meeting today?

20 CHAIRMAN CRAWFORD: You mean today or  
21 sometime in their life?

22 (Laughter.)

23 MR. BRISCOE: Today, today. No.  
24 Today.  
25 Every day is a new day. And you need to exercise

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 every day.

2 CHAIRMAN CRAWFORD: Okay. Thank you  
3 very  
4 much.

5 MR. BRISCOE: You're welcome.

6 (Applause.)

7 VICE CHAIRMAN LEVITT: Our next speaker  
8 is  
9 Lyn O'Brien Nabors, Executive Vice President,  
10 Calorie  
11 Control Council.

12 MS. NABORS: Thank you.

13 The Calorie Control Council is an  
14 international association representing the  
15 manufacturers of low-calorie and reduced-fat foods  
16 and  
17 beverages. We also represent the companies that  
18 make  
19 low-calorie sweeteners, low-calorie bulking agents,  
20 and fat replacers. I, Lyn Nabors, Executive Vice  
21 President, am pleased to present the following  
22 comments on behalf of the Calorie Control Council.

23 Secretary Thompson, recently addressing  
24 the 2005 Dietary Guidelines Advisory Committee,  
25 noted

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1 that he comes from a state that likes milk, cheese,  
2 beer, and bratwurst and asked the committee if they  
3 could make them with fewer calories. Well, the  
4 good  
5 news is such products already exist, along with  
6 hundreds of other good-tasting, low-calorie, and  
7 reduced-calorie foods and beverages. The bad news  
8 is  
9 the consumers may not be using these products  
10 appropriately.

11 According to the Calorie Control  
12 Council's  
13 most recent consumer research on light product  
14 usage,  
15 87 percent of Americans say that they use light  
16 products on a regular basis. And in this instance,  
17 regular basis was defined as once every two weeks.

18 The majority of users consume these  
19 products several times a week and say they want  
20 more.

21 However, 36 percent of those who say they need to  
22 lose  
23 weight admit that they often splurge on their  
24 favorite  
25 full-calorie foods.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com



1                   Dr. Jim Hill of the University of  
2 Colorado  
3 recently reported that people are gaining an extra  
4 2  
5 pounds per year, or 14 to 16 pounds over an 8-year  
6 period. He notes that a simple approach to  
7 preventing  
8 this weight gain is to cut out just 100 calories  
9 per  
10 day. This cut of 100 calories per day can be done  
11 by  
12 using reduced-calorie products in place of their  
13 full  
14 calorie counterparts.

15                   For example, simply substituting a  
16 packet  
17 of low-calorie tabletop sweetener for sugar in  
18 coffee,  
19 on cereal, and in iced tea three times a day is  
20 about  
21 a savings of 100 calories. Consuming eight ounces  
22 of  
23 a light yogurt sweetened with low-calorie  
24 sweeteners  
25 in place of a low-fat yogurt saves about 140

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

1 calories.

2                   Choosing a cup of skim milk in place of  
3 whole milk saves 60 calories.     Substituting a  
4 serving  
5 of sugar-free gelatin for the regular gelatin saves  
6 about 70 calories.     Using fat-free chips in place  
7 of  
8 regular potato chips saves 75 calories per ounce.  
9 And  
10 replacing a regular soda with a diet soda saves  
11 about  
12 150 calories.     The list goes on and on.

13                   It's well-known that weight loss is the  
14 result of expending more calories than consumed.  
15 Additional calories would need to be cut from the  
16 diet  
17 and activity increased, preferably both, in order  
18 to  
19 lose weight.

20                   Low-calorie sweeteners and the products  
21 containing them provide sweetness and good taste  
22 without the calories of their full-calorie  
23 counterparts.     Research demonstrates that when  
24 sucrose  
25 is covertly replaced with low-calorie sweeteners,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 non-dieting obese and normal weight individuals  
2 incompletely compensate for the caloric reduction.

3 In  
4 other words, they consume fewer calories.

5           Importantly, a three-year scientific  
6 study  
7 conducted at Harvard Medical School showed that the  
8 low-calorie sweetener Aspartame was a valuable aid  
9 to  
10 a long-term weight management program that included  
11 diet, exercise, and behavior modification.

12           A recent study to determine the impact  
13 of  
14 reduced-calorie foods and beverages; that is,  
15 products  
16 that were sweetened with low-calorie sweeteners,  
17 was  
18 undertaken to determine the quality of the diet of  
19 American adults. The micronutrient quality of the  
20 diet of those using reduced-calorie products  
21 containing low-calorie sweeteners was significantly  
22 better than those who did not use such products,  
23 and  
24 the energy intake was reduced.

25           Clearly, there are significant benefits

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4100

www.nealr.com

1 when products reduced in calories are incorporated  
2 into a sensible diet. Today the council proposes  
3 labeling that would make reduced-calorie foods more  
4 attractive to consumers and allow food and beverage  
5 manufacturers to position their products more  
6 favorably.

7 The proposed labeling would also assist  
8 in  
9 educating consumers about the risk of obesity and  
10 the  
11 important role that reduced-calorie products can  
12 play.

13 Thus, please consider the following.  
14 Using reduced-calorie or micronics as appropriate  
15 to  
16 the product, we're talking about using  
17 reduced-calorie  
18 foods and beverages limited in fat and calories in  
19 foods and beverages as part of the diet may reduce  
20 the  
21 risk of obesity. Obesity increases the risk of  
22 diabetes, heart disease, and certain cancers.

23 We trust the FDA will give serious  
24 consideration to this proposed qualified health  
25 claim.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 The council will formally proposed such labeling to  
2 the agency shortly along with additional supporting  
3 data.

4 Thank you.

5 (Applause.)

6 CHAIRMAN CRAWFORD: Thank you for that  
7 presentation.

8 What is the single thing within the  
9 authority that the FDA has or the government in  
10 general, the single thing you think we could do  
11 that  
12 would help with this current situation?

13 I take it you agree that we have a  
14 public  
15 health problem of epidemic proportions. And I take  
16 it  
17 everybody does that is here. What is something  
18 that  
19 you think would make a difference? That's really  
20 the  
21 kind of thing we need.

22 MS. NABORS: That's not a simple  
23 question.

24 CHAIRMAN CRAWFORD: No. This is not a  
25 simple situation.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 MS. NABORS: No, it's not. And I think  
2 that my response to that would be consumer  
3 education.

4 I'm not sure I can tell you exactly how you do  
5 that,  
6 but I think that the consumers really don't know  
7 what  
8 calories are. Even if you gave them the  
9 information,  
10 sometimes when you give them appropriate  
11 information,  
12 the consumer doesn't know what to do with it.

13 CHAIRMAN CRAWFORD: Do you think the  
14 nutrition label as it currently exists is not  
15 enough?

16 MS. NABORS: I have some concern about  
17 putting too much information on a food label to the  
18 point that it's confusing. There's just so much  
19 there  
20 that people don't read it or it looks messy.

21 CHAIRMAN CRAWFORD: By "education," you  
22 are talking about like print media and use of  
23 public  
24 service announcements and that sort of thing?

25 MS. NABORS: Yes. And I think you need

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

1 to  
2 start with the children and the parents because, as  
3 somebody mentioned earlier, I think we learn to eat  
4 what we eat when we are children. I mean, comfort  
5 food is a good example.

6 CHAIRMAN CRAWFORD: Right.

7 MS. NABORS: The things that you grow  
8 up  
9 with are the things that you continue to eat and if  
10 we  
11 can educate the children and the mothers about the  
12 appropriate things to give their children.

13 CHAIRMAN CRAWFORD: Thank you.

14 VICE CHAIRMAN LEVITT: Our next speaker  
15 is  
16 Dr. Susan Finn, Chair, American Council for Fitness  
17 and Nutrition. Welcome.

18 DR. FINN: Thank you very much. It is  
19 a  
20 pleasure to be here. I am glad you are all here  
21 with  
22 us, even though the hour is late. It is a pleasure  
23 to  
24 be here and to be able to have the opportunity to  
25 express the views of the American Council for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 Fitness  
2 and Nutrition.

3 As you recall, when Alison Kretser  
4 spoke  
5 with the GMA, she indicated this is one of the two  
6 strategies and approaches that the food and  
7 beverage  
8 industry is using as it participates with you all  
9 in  
10 helping to come up with solutions to this epidemic  
11 problem that we're all dealing with today.

12 The American Council of Fitness and  
13 Nutrition, which we fondly refer to as ACFN,  
14 acknowledges, like you all do, that it is a growing  
15 concern for all Americans. We also acknowledge, as  
16 you all have, that it is a complex issue  
17 representing  
18 a multitude of factors related to diet, physical  
19 activity, attitudes about nutrition and fitness,  
20 cultural and family traditions, changing  
21 lifestyles,  
22 and even the design of our neighborhoods.

23 For these reasons, it is obvious we are  
24 all part of the problem. Families, schools,  
25 communities, policy-makers, and the food and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com



1 beverage  
2 industry all have a very important role to play in  
3 combatting this problem.

4 In January of 2003, the American  
5 Council  
6 of Fitness and Nutrition was formed by a coalition  
7 of  
8 food and beverage companies, restaurants,  
9 advertisers,  
10 related trade associations, and other interested  
11 groups.

12 Today ACFN is a not-for-profit  
13 organization representing more than 40  
14 organizations,  
15 like the American Dietetic Association, all who  
16 support ACFN's mission to work with public  
17 policy-makers at the national, state, and local  
18 level  
19 to advocate for realistic long-term solutions to  
20 the  
21 nation's growing obesity epidemic and to promote  
22 some  
23 of the very best examples of things that do work.

24 As the Chair of the American Council  
25 for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 Fitness and Nutrition and past President of the  
2 American Dietetic Association, I have committed my  
3 time and efforts to working with you all and other  
4 policy-makers to provide families, schools, and  
5 communities with information and resources needed  
6 to  
7 address obesity, particularly for customers and for  
8 individuals on their own terms.

9 The emerging consensus is that obesity  
10 solutions must address both diet and activity.  
11 This  
12 will require FDA to work with all stakeholders,  
13 including the food industry and the business  
14 community, to make the best use of existing  
15 resources  
16 and programs.

17 Furthermore, these efforts must focus  
18 on  
19 programs and policies that really empower consumers  
20 to  
21 make the very best choices for their own personal  
22 health and their own nutrition goals, allowing them  
23 to  
24 find a long-lasting healthy balance for life.

25 The FDA is to be commended for its work

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 in  
2 doing just that. Regulations for qualified health  
3 claims and the trans fat labeling are just two of  
4 the  
5 examples where FDA has stepped forward to provide  
6 consumers with accurate information about  
7 nutrition.

8 And thank you for that. These regulations will  
9 provide food and beverage companies with one more  
10 reason to develop even more nutritious foods.

11 FDA should not underestimate the power  
12 of  
13 competition. As with the agency's challenge to  
14 industry to develop and market more reduced fat and  
15 fat-free products in the 1990s, you can be assured  
16 that the industry will respond to the challenge of  
17 providing consumers with products that can make  
18 positive claims about the nutritional benefits for  
19 consumers.

20 American Council for Fitness and  
21 Nutrition  
22 also encourages the FDA to assess what gaps in  
23 research exists regarding obesity's causes and  
24 solutions, particularly in the behavior aspects.  
25 This

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 can be done even through projects on their own or  
2 by  
3 partnering with agencies or with the private sector  
4 organizations.

5 A thorough assessment of the gaps in  
6 the  
7 existing obesity research would provide the FDA and  
8 others with a much better understanding of what the  
9 next steps are in combatting obesity. And this  
10 morning we were pleased to hear that NIH is taking  
11 such a step.

12 The industry is firmly committed to  
13 partnering with FDA to promote effective policies  
14 aimed at improving nutrition information and  
15 encouraging regular physical activity. The  
16 industry  
17 acknowledges the role it plays in providing  
18 consumers  
19 with many foods and beverages they enjoy every day  
20 and  
21 is committed to doing its part to help consumers to  
22 better understand how they have to balance what  
23 they  
24 eat with what they do.

25 The industry's commitment includes

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 investing in innovative product research and  
2 research  
3 into nutritious products, providing consumers with  
4 products to meet their health needs and goals,  
5 assessing portion size and packaging, responsible  
6 advertising, and marketing practices, and certainly  
7 walking the talk by supporting their own health and  
8 wellness programs for their own employees.

9 In recent months, the industry has made  
10 great strides in many of these areas. And I'm sure  
11 you all have read about some of these. Companies  
12 such  
13 as Coca-Cola, General Mills, Kraft, Mott's,  
14 PepsiCo,  
15 and others have introduced so-called "better for  
16 you"  
17 products. These include new milk-based drinks,  
18 reduced-calorie juices, trans fat-free snacks to  
19 name  
20 just a few.

21 And restaurants like Applebee's,  
22 McDonald's, the Olive Garden, and Wendy's are also  
23 contributing to these efforts by launching  
24 partnerships and by offering new menu options, such  
25 as

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 salads and reduced-fat meals. Other industry  
2 efforts  
3 include reviewing what constitutes an appropriate  
4 size  
5 for a single serve package, increasing the amount  
6 of  
7 nutrition information available in restaurants, and  
8 providing employees with access to their on-site  
9 fitness centers within their facilities.

10           The American Council for Fitness and  
11 Nutrition also promotes the fitness and nutrition  
12 programs and policies that you all know about:  
13 Hearts  
14 in Parks; P.E. for Life; America on the Move; and  
15 the  
16 Department of Education's Carol M. White Physical  
17 Education Program grants; and, of course, HHS'  
18 Healthier U.S. initiative.

19           As the FDA considers its own community  
20 outreach programs, we recommend that the FDA  
21 partner  
22 with one or more of these programs in order to  
23 maximize existing resources and establish  
24 community-based programs that are effective and  
25 long-term solutions to obesity.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1                   At the end of the day, any regulation  
2                   or  
3                   new initiative should help consumers lead healthy  
4                   and  
5                   active lives and be able to make wise choices. The  
6                   information about these efforts should also be  
7                   understandable and relative to how families and  
8                   Americans live, rather than expecting them to make  
9                   full-scale changes to their lives.

10                   We believe this approach is compatible  
11                   with the administration's Healthier U.S. initiative  
12                   as  
13                   well as Secretary Thompson's stated goals of  
14                   showing  
15                   both children and adults the enjoyable and doable  
16                   steps they can take to better health.

17                   As ACFN looks at ways for industry at  
18                   large to combine forces to help combat obesity, the  
19                   American Council for Fitness and Nutrition can  
20                   provide  
21                   a framework for broader industry collaboration and  
22                   partnerships with the FDA. We look forward to  
23                   working  
24                   with you and your agency as it continues to develop  
25                   its own strategy for helping to develop a healthier

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 America.

2 Thank you very much.

3 (Applause.)

4 CHAIRMAN CRAWFORD: Can I ask you just  
5 one  
6 quick thing?

7 DR. FINN: Sure.

8 CHAIRMAN CRAWFORD: In dealing with  
9 fitness and nutrition and also the exercise habits  
10 of  
11 Americans, how do you react to the fact that in  
12 1970  
13 to '75, there was the so-called tennis boom or  
14 exercise boom or fitness boom or jogging? I  
15 remember  
16 very well new tennis courts being built in  
17 municipalities, waits in line to play tennis of an  
18 hour and a half or more, and so forth and so on.

19 DR. FINN: Right.

20 CHAIRMAN CRAWFORD: Then just a few  
21 years  
22 later, you could have put away the tennis courts  
23 and  
24 made picnic areas out of them. So it seemed like  
25 exercise was in vogue for a while. Then it went

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com



1 away.

2 Is that correct? And what do we do to get it back?

3 DR. FINN: Yes. I think when you look

4 at

5 the data, it clearly a very small percentage of our

6 population do regular physical activity and regular

7 exercise. I think clearly what has happened is we

8 are

9 just busy. We are busy until we have to make it

10 doable and good for and easy for people.

11 And that's why the little pedometers,

12 like

13 the one I am wearing. And I have been very

14 inadequate. I've only got 2,000 steps. And I have

15 been up since 4:00. So I've got some work to do

16 yet.

17 But I think you have got to make it easy and it

18 fits

19 in with folks' lives.

20 Thanks.

21 CHAIRMAN CRAWFORD: Thank you.

22 VICE CHAIRMAN LEVITT: Thank you very

23 much.

24 We are coming down the home stretch, so

25 to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 speak, and welcome our next speaker, Dr. Gregory  
2 Miller, Senior Vice President, Nutrition and  
3 Scientific Affairs, National Dairy Council.

4 DR. MILLER: Good afternoon. And I  
5 would  
6 like to thank the committee as well for the  
7 privilege  
8 to be here today.

9 Les, by the way, I have written a book  
10 as  
11 well, too. And I will make sure you get a copy. I  
12 think you will find it has a larger breadth of data  
13 in  
14 it and more balanced approach to the science. So  
15 we  
16 will make sure you get a copy.

17 CHAIRMAN CRAWFORD: Thank you.

18 DR. MILLER: We commend the FDA and the  
19 Obesity Working Group for undertaking such an  
20 important initiative. As obesity is one of the key  
21 health issues facing America today, for more than  
22 85  
23 years, the National Dairy Council has worked to  
24 advance the state of scientific knowledge on the  
25 role

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 and value of dairy foods in promoting and enhancing  
2 human nutrition and health. We look forward to  
3 assisting you in any way possible to help build  
4 diets  
5 that promote health, prevent disease, and maintain  
6 ideal body weight.

7           You asked for comments on six questions  
8 specific to developing solutions to the obesity  
9 problem in America. Before I address some of those  
10 questions, I have a few over-arching comments that  
11 I  
12 would like to make, as many others have.

13           First, though there are many tools  
14 available to help consumers make better diet  
15 decisions, including the dietary guidelines and  
16 USDA's  
17 food guide pyramid, Americans are not following the  
18 government's nutrition recommendations. Only one  
19 to  
20 three percent of Americans are actually following  
21 the  
22 pyramid.

23           However, this does not necessarily mean  
24 that the tools are ineffective. It illustrates  
25 that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 Americans need more help turning this information in  
2 those guidelines into action for better health.

3 One way to do it is to simplify  
4 consumer  
5 education materials by including consistent  
6 information. For example, if the food guide  
7 pyramid,  
8 dietary guidelines, and food labels, including the  
9 nutrition facts panel, used the same serving size  
10 references, you could project that Americans could  
11 more easily build a pyramid-based diet by using the  
12 information on the nutrition facts panel in the  
13 foods  
14 they purchase.

15 Today that's not possible. As an  
16 example,  
17 a consumer purchasing processed cheese, for  
18 example,  
19 would see one slice as a serving size on the  
20 package,  
21 but this does not match the USDA serving size in  
22 the  
23 food guide pyramid expectation that that serving of  
24 dairy will provide 300 milligrams of calcium.

25 Consistency in information like serving

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 sizes might promote behavior change and help to  
2 close  
3 the large gap between recommendations and  
4 compliances.

5           Second, in Tommy Thompson's recent  
6 remarks  
7 at the National Food Policy Conference and as we  
8 heard  
9 today, he said so many of our chronic, debilitating  
10 illnesses can be prevented through lifestyle  
11 choices.

12 The staggering statistics demonstrate that  
13 Americans  
14 do not fully comprehend what they eat and what they  
15 do  
16 or don't do with physical activity over a period of  
17 time and how that translates into their weight.

18           Helping Americans, especially children,  
19 understand energy balance and how to select foods  
20 to  
21 build a nutritionally adequate diet that is  
22 appropriately balanced for the level of energy  
23 expended could go a long way toward prevention of  
24 obesity and its many related diseases.

25           Today food labels focus on energy in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 but  
2 not on the other half, as we have heard from other  
3 speakers today: how to balance it with energy out.  
4 Labels could be an important tool in the prevention  
5 of  
6 obesity and related diseases by helping consumers  
7 understand the concept of energy balance so that  
8 they  
9 can more easily select foods to build a  
10 nutritionally  
11 sound diet that is appropriately balanced for  
12 energy  
13 level in and energy level expended.

14 Finally, there will be many great ideas  
15 that come out of today's meetings and subsequent  
16 written comments to FDA for consideration, but we  
17 know  
18 there is no single answer, no easy answer. We  
19 recommend for you to use a scientific,  
20 evidence-based  
21 approach to energy balance. I want to reiterate  
22 that,  
23 scientific-based, evidence-based approach, that is  
24 going to be critical to ensure that the best, most  
25 accurate health information will be delivered to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 Americans.

2                   We also commend your continued  
3 enforcement  
4 of fraudulent weight loss claims, which will help  
5 reduce consumer confusion, directing them toward  
6 positive lifelong changes for weight loss and  
7 overall  
8 better health.

9                   Now I would like to address some of  
10 your  
11 specific questions, particularly obviously as they  
12 relate to dairy. In response to question three on  
13 the  
14 available evidence to guide public efforts to  
15 prevent  
16 and treat obesity.

17                   A gray body of evidence indicates that  
18 melted cheese and yogurt may play a role in weight  
19 management efforts when coupled with a  
20 calorie-controlled diet. As the nation focuses on  
21 preventing obesity and weight gain, it is important  
22 for consumers to understand that dairy products,  
23 partially due to their high calcium content, may  
24 play  
25 an important role in the regulation of energy

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 metabolism, resulting in a reduction in body fat  
2 and  
3 an acceleration of weight and fat loss during  
4 calorie  
5 restriction.

6 A number of studies over the past five  
7 years have looked at this connection. We have  
8 randomized clinical control trials that demonstrate  
9 this clearly.

10 The current science indicates that  
11 increasing dairy intakes to adequate levels -- and  
12 in  
13 the randomized clinical trials, it was three to  
14 four  
15 servings -- can enhance the effectiveness of a  
16 balanced, reduced-calorie diet for weight and body  
17 fat  
18 loss. While more research continues to unfold, the  
19 science is important as it relates to prevention  
20 and  
21 treatment of obesity.

22 I would like to address questions four  
23 and  
24 five together, changes in food labeling to develop  
25 and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com



1 promote lower-calorie foods and opportunities that  
2 exist for the development of healthier foods.

3 Science and history show that  
4 one-dimensional strategies, such as low-calorie or  
5 low-fat, do not provide a magic bullet for the  
6 development of better diets for weight management.

7 We have already undergone years of  
8 low-fat  
9 and fat-free. And, yet, Americans have gained more  
10 weight than ever. Promotion and development of  
11 low-calorie foods alone will not prevent reduced  
12 rates  
13 of obesity.

14 It's scary to think, but if you take a  
15 low-calorie focus to the extreme, individuals could  
16 eat low-calorie foods and still suffer from a host  
17 of  
18 chronic diseases precisely because they are not  
19 getting the nutrients they need to promote health  
20 or  
21 prevent disease. One could project that this  
22 approach  
23 could continue to distort consumer behavior, rather  
24 than help educate consumers on the right balance of  
25 foods and physical activity for a healthy weight.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 This would result in consumers who are overfed but  
2 undernourished.

3           People eat foods. It's not the number  
4 of  
5 calories on the nutrition facts panel or the energy  
6 density of the individual food that builds a  
7 nutritious diet. The overall nutrition and health  
8 benefits that those calories deliver is what really  
9 matters, balance with the appropriate physical  
10 activity.

11           Dairy foods have been shown to be  
12 important for bone health. As I mentioned a minute  
13 ago, we are learning that nutrients in dairy that  
14 are  
15 good for bones may also be good for weight  
16 management.

17           Clinical trials have shown that calcium  
18 and other nutrients in dairy may play an important  
19 role in helping to reduce weight and body fat.  
20 Additionally, studies have shown that people who  
21 follow moderate-fat diets have better compliance  
22 and  
23 success with weight management.

24           Nutritious foods, like dairy, that  
25 science

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 shows can help control body fat and deliver a  
2 variety  
3 of important nutrients are part of the solution.  
4 This  
5 is important for consumers to know. Food labels  
6 and  
7 other educational tools can help consumer build  
8 healthier, not just lower-calorie, diets that  
9 optimize  
10 personal energy balance and help maintain weight.

11 I will gleefully address question six  
12 about the most important things FDA could do to  
13 make  
14 a significant difference in the obesity effort.  
15 I'm  
16 sure we all agree that physical activity should be  
17 a  
18 main area of focus.

19 Forty percent of adults 18 and over  
20 engage  
21 in no leisure time physical activity, and only 23  
22 percent report regular vigorous exercise three or  
23 more  
24 days a week. When you combine Americans' low  
25 energy

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 output with high energy intake and tack on the gap  
2 between nutrition recommendations and consumer  
3 compliance, it paints a grim picture.

4 Properly regulated through a scientific  
5 evidence-based process, the FDA's on-label  
6 qualified  
7 health plans will create more awareness of emerging  
8 science and help consumers make more informed  
9 decisions about the foods they choose.

10 We might begin tackling the obesity  
11 epidemic with the following implementation  
12 considerations. Consistent information across  
13 educational tools, such as serving sizes, a focus  
14 on  
15 prevention by helping consumers understand the  
16 concept  
17 of energy balance on labels so that they can turn  
18 it  
19 into an action plan suitable for their individual  
20 lifestyles.

21 A communications plan to convey the  
22 information in a consumer-relevant way with  
23 multiple  
24 touch points from labels to marketing to government  
25 nutrition guidelines, as we heard earlier from one

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 of  
2 our speakers, in a surround sound kind of approach;  
3 scientific evidence-based solutions for selecting  
4 food  
5 and building diets that are part of the solution to  
6 weight management, again, scientific and  
7 evidence-based; a pilot test to determine the  
8 effectiveness and feasibility of any proposed plan  
9 before serving it up to Americans. And look for  
10 opportunities to collaborate with existing  
11 programs;  
12 for example, the action for Healthy Kids, which has  
13 state teams working to create a healthy school  
14 environment by promoting nutrition education,  
15 physical  
16 activity, and other types of programs within the  
17 schools to create a healthy school environment.  
18 The  
19 combination of these things could start to make a  
20 sizable difference in the prevention and treatment  
21 of  
22 obesity.

23 As you work toward solutions to the  
24 problems of obesity, please do not hesitate to  
25 contact

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 me or my organization if you would like additional  
2 information or if there is anything we can do to  
3 support you. Thank you for your consideration.

4 (Applause.)

5 CHAIRMAN CRAWFORD: You mentioned that  
6 we  
7 do a good job of energy in on the label, I think  
8 you  
9 mentioned, but not energy out. Is there a way to  
10 do  
11 that on the labels, I mean, or in some reasonable  
12 way  
13 within the confines of what we do under NLEA?

14 DR. MILLER: I believe that we're smart  
15 enough to figure out how to do that. I don't know  
16 the  
17 answer. But I think with consumer research, we  
18 have  
19 got smart people in the food industry, in  
20 government,  
21 in other health professional groups that can figure  
22 it  
23 out.

24 CHAIRMAN CRAWFORD: That was the  
25 concept

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com

1 you were proposing, though?

2 DR. MILLER: Yes, sir.

3 CHAIRMAN CRAWFORD: Okay. Thank you.

4 VICE CHAIRMAN LEVITT: Thank you.

5 Our next speaker is Dr. Mary Enig from  
6 Weston A. Price Foundation.

7 DR. ENIG: Good afternoon. Thank you,  
8 panel, for giving me this opportunity to present  
9 some  
10 information, and ladies and gentlemen in the  
11 audience.

12 My name is Mary Enig. I have a Ph.D.  
13 in  
14 nutritional sciences from the University of  
15 Maryland.

16 And I am serving today as the Vice President of the  
17 Weston A. Price Foundation and its science adviser.

18 During my period of tenure at the  
19 University of Maryland, I did the initial trans  
20 fatty  
21 acid research identifying how much trans there was  
22 in  
23 the food supply. I actually was not the first  
24 person  
25 to suggest that it needed to be done, although I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 did  
2 not know about the FDA's internal memo in 1970  
3 until  
4 sometime in the 1990s. However, I also found out  
5 that  
6 what they had suggested I did.

7 Now, I want to address the topic of  
8 food  
9 fats. And I am going to be taking a slightly  
10 different approach because their impact on health  
11 represents a very important nutrient about which  
12 there  
13 is massive misinformation.

14 Misinformation has been presented to  
15 the  
16 public since 1969. I have followed it since the  
17 early  
18 1970s. This misinformation is promoted in the  
19 form,  
20 unfortunately, of the U.S. dietary goals and  
21 guidelines. And it's been largely responsible for  
22 promoting an unbalanced intake of the fat  
23 components  
24 in our diets.

25 Natural fats, such as butter, tallow,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrsgross.com



1 lard, and palm and coconut oils, had been relegated  
2 to  
3 the garbage heap. And the replacement manmade  
4 fats,  
5 such as the widely used, partially hydrogenated  
6 shortenings and margarines and excessive Omega 6  
7 polyunsaturated oils, had been promoted as if they  
8 were magic medicine. This is just the opposite of  
9 what we should be doing.

10 Those natural fats and oils listed  
11 above  
12 have important components found only in them.  
13 These  
14 components are health-promoting. And their  
15 replacements are now known to be disease-causing.

16 The 1969 White House conference on  
17 foods  
18 and nutrition produced the new foods document,  
19 which  
20 promoted the acceptance of imitation foods as if  
21 they  
22 were real foods. This has led to a major decline  
23 in  
24 the quality of our foods and especially in the  
25 quality

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 of food fats. It has led to open promotion of  
2 genetically modified foods that suit the production  
3 of  
4 processed fats and has also led to a decline in  
5 quality and uses of our farm-produced animal fats.

6 We are confronted with the problems of  
7 widespread obesity, runaway diabetes in adults, and  
8 increasingly in children, ever-increasing cancer  
9 incidence rates, immune dysfunction, a continuing  
10 increase in heart disease incidence rates, and  
11 growth  
12 and development problems in our young.

13 In 1970, the FDA prepared an internal  
14 memo  
15 that said, "The trans fatty acids in the food  
16 supply  
17 should be identified." More than 30 years later,  
18 the  
19 FDA proposed the cloudy labeling of the trans fats  
20 under an unsuitable saturated fats umbrella.

21 In the intervening 30 years, during  
22 part  
23 of which I was a fats and oils and lipids  
24 researcher  
25 at the university lipids laboratory in College

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 Park,  
2 I had frequently pointed out to various agencies to  
3 reports to the appropriate dockets that ignoring  
4 the  
5 levels of trans fatty acids in foods has prevented  
6 us  
7 from having accurate data on fat composition of our  
8 diets.

9 As a result of being misled, we have a  
10 consuming public terrified of natural fats and  
11 oils,  
12 a public which by its avoidance of these natural  
13 saturated fats and oils and its consumption of the  
14 fabricated, man-manipulated fats and oil  
15 replacements,  
16 such as the trans fats and the unstable  
17 polyunsaturates, is becoming increasingly obese and  
18 ill.

19 In 1993, a University of Pittsburgh  
20 researcher Color who published in the Lancet, 341  
21 page  
22 1,093, reported that women who consumed more trans  
23 fatty acids were several kilograms heavier than  
24 women  
25 who consumed less trans, even though the calorie

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 intake was the same for both groups.

2 Other research over the last several  
3 decades has pointed to the involvement of the Omega  
4 6  
5 polyunsaturates in increasing fat cells. This is  
6 the  
7 work of Jay Rulan in France.

8 And recent work by Pan and Sterling,  
9 again  
10 published in 1993, shows that Omega 3 fatty acids  
11 are  
12 needed to avoid weight gain. Trans fatty acids  
13 promote the adverse effects of linoleic acid, the  
14 common Omega 6 polyunsaturate, and decrease the  
15 important Omega 3 fatty acids in the tissue. The  
16 natural saturates actually protect the Omega 3  
17 fatty  
18 acids.

19 This attempt by the FDA to tar the  
20 wholesome saturated fats with the sins of the trans  
21 fats so as to promote in the minds of consumers the  
22 idea that they are both the same is not supported  
23 by  
24 real science. Biologically the saturates and the  
25 trans have totally opposite effects. The effects

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 of  
2 the saturates are good, and those of the trans are  
3 undesirable.

4 Many of you at this meeting may not  
5 have  
6 been born in 1969. Those of us who were adults at  
7 that time know the extent to which the new foods  
8 really are imitation foods, even though they are  
9 not  
10 labeled as such.

11 The consumption of these imitation  
12 foods  
13 needs to be looked at very carefully for the role  
14 they  
15 play in causing overeating and consequent obesity.

16 It  
17 is the lack of natural fats in the current diets  
18 that  
19 leads to inappropriate hunger, and only appropriate  
20 research can verify that this is so.

21 There have been a couple of comments  
22 that  
23 the research needs to be very carefully done. A  
24 lot  
25 of the research has not been that carefully done.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1           In addition to promoting obesity by the  
2 loss of satiety values from natural, more saturated  
3 fats, there is also a loss of the only reliable  
4 source  
5 of vitamin D, namely the more saturated animal  
6 fats.

7 Vitamin D has recently become very much recognized  
8 as  
9 a nutrient that is missing from a lot of the diets.

10           I have a couple of essays that I  
11 brought  
12 with me that I am going to make some comments from.  
13 These essays are on the Weston A. Price Foundation  
14 Web  
15 site. One of them is titled "Why the Current U.S.  
16 Dietary Guidelines are Making Americans Fat." It  
17 has  
18 some very specific references. The other one  
19 addresses low-fat diets. And it has a series of  
20 references.

21           One of the items from the current U.S.  
22 dietary guidelines problem is that the McGovern  
23 committee on dietary, the select committee, got  
24 information from people that was not correct. That  
25 information was then picked up and put into a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 document  
2 that became part of a farm bill. That ended up  
3 making  
4 the amounts of research that could be requested  
5 from  
6 the public limited to what was in the wording in  
7 the  
8 farm bill. I suggest that some of you may want to  
9 look into this. Those of you who are still in  
10 active  
11 research may find this a very interesting topic to  
12 dedicate some time to.

13           The other thing that I want to talk  
14 about  
15 with respect to the low-fat diets is that if you  
16 look  
17 at what constituted fat in the diets in the 1920s  
18 and  
19 the 1930s, you would find that low-fat, generally  
20 speaking, was about 30 percent or a little bit more  
21 of  
22 the calories. That was low-fat. Regular fat  
23 ranged  
24 from 35 to 45 percent of the calories as fat.

25           And if you had people who were

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1       convalescing, they had to have much, much higher  
2       amounts of fats.  However, all of these fats were  
3       the  
4       natural fats that came with the foods.  These were  
5       the  
6       fats that were in the meat that went into the  
7       stews.

8       These were the fats that were in the milk that were  
9       part of what children grew up drinking and adults  
10      drank.  And they went into the cheese that people  
11      ate.

12     And the amounts of fat that were unnatural fats,  
13     manmade fats that caused problems were very, very  
14     limited.

15                     Now, people say, "Oh, but saturated  
16     fats  
17     cause all sorts of problems."  Saturated fats are  
18     not  
19     understood for what they really are.  Basically,  
20     within diets, we have more or less three saturated  
21     fatty acids:  stearic acid, palmitic acid, and  
22     myristic acid.  I want to tell you something about  
23     at  
24     least two of those fatty acids, that those of you  
25     who

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4122

www.nealrsgross.com



1 are involved in research might want to think a  
2 little  
3 bit more about doing something about.

4 Palmitic acid is the acid that the body  
5 uses for putting into the membranes, a lot of the  
6 membranes in the brain, in the body, but especially  
7 in  
8 the lungs, fatty acid that goes into lung  
9 surfactant.

10 Lung surfactant is what is called  
11 dipalmitoylphosphatidylcholine. That fatty acid is  
12 palmitic acid.

13 Sometimes people say, "Oh, well. We  
14 can  
15 make palmitic acid because that is the fatty acid,  
16 the  
17 basic fatty acid, that the body makes."

18 But there has been some research lately  
19 that has shown that if you take youngsters, young  
20 animals, and feed them a diet devoid of palmitic  
21 acid,  
22 they end up with problems in their immune systems.  
23 And their lungs don't function properly. So that  
24 we  
25 can't necessarily make as much of the palmitic acid

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 as  
2 we really need. Now, palmitic acid, of course, is  
3 found in the dairy fats, found in palm oil, found  
4 in  
5 animal fats.

6           There is another fatty acid that is  
7 considered by people to be the worst fatty acid  
8 there  
9 is. And that is myristic acid. Myristic acid is  
10 found in the lauric oils, like coconut oil and palm  
11 kernel oil. It's found in fish fats, meat oils, in  
12 small amounts in meat oils, in small amounts in  
13 fish  
14 oils. And myristic acid is used by the body for  
15 stabilizing proteins and for what is called energy  
16 transduction.

17           So that if you don't have any or  
18 practically no myristic acid coming in in your  
19 diet,  
20 you will end up with some potential problems. And  
21 the  
22 fact that people are being told to avoid diets that  
23 will provide myristic acid, palmitic acid, to a  
24 certain extent stearic acid is something which is  
25 extremely unfortunate because the people who are

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 telling you to avoid these fatty acids, to avoid  
2 these  
3 evil saturates don't know what they're talking  
4 about.

5 They don't understand the science behind how the  
6 body  
7 uses fats.

8                   The body uses fats to put into brain  
9 cells  
10 for all of the parts of the brain where there is  
11 fat.

12 About half of it or close to half of it, 46  
13 percent,  
14 is saturated. For the other membranes that are in  
15 all  
16 of the cells, half of the fatty acids that go into  
17 the  
18 phospholipids are saturated. They're usually  
19 either  
20 palmitic acid or stearic acid.

21                   So if you're wondering about how the  
22 body  
23 uses saturated fatty acids, what happens is that it  
24 is  
25 supposed to be there. And if it's not there, then

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealrsgross.com

1 many things don't work well. But more than that,  
2 if  
3 it's not there because you're not consuming an  
4 adequate amount of the saturates, what is it that  
5 you  
6 are consuming? What you are coming is excess  
7 polyunsaturates and excess trans fatty acids.

8           Those people who think that there is  
9 practically no trans fatty acid in most of the  
10 diets  
11 and think that it is only a couple of percent are  
12 really wrong because, as a matter of fact, we have  
13 documented at the University of Maryland when I was  
14 there much, much higher percents than that. And  
15 they  
16 have documented much higher percents than that in  
17 Europe, up to 40-50 grams a day in adults. And  
18 sometimes in youngsters, I have documented up to  
19 100  
20 grams a day because they were consuming the kinds  
21 of  
22 foods that had high levels of the trans fatty  
23 acids.

24           Well, when you take trans fatty acids  
25 into

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 your system, you end up having them accumulate in  
2 those parts of the tissue where you normally should  
3 be  
4 having saturated fatty acids. And if you don't  
5 have  
6 the saturated fatty acids and you have the trans  
7 fatty  
8 acids or you have excess of the polyunsaturated  
9 fatty  
10 acids that are in the Omega 6 family, which is  
11 where  
12 a lot of your fatty acids are found, you also have  
13 another situation where you can end up with a lot  
14 of  
15 free radical formation and you don't have enough of  
16 the Omega 3 fats.

17 So I think that one of the things that  
18 needs to be looked at very carefully is the extent  
19 of  
20 the trans fatty acid in those diets where the  
21 individuals have resulted in obesity. That has  
22 never  
23 really been looked at very carefully.

24 I understand from some of the people I  
25 have talked to about what should we be doing about

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 this kind of research is that they can't get funds  
2 for  
3 this. Of course, they can't get funds for this  
4 because nobody wanted anybody to really know how  
5 much  
6 of a problem these processed fats were.

7 So I would suggest that for those of  
8 you  
9 who want to go on to the internet who want to read  
10 a  
11 little bit about the documentation of some of the  
12 things that I have presented to you, you will find  
13 them on the Weston A. Price Foundation Web site.  
14 And  
15 that's [www.westonaprice.org](http://www.westonaprice.org).

16 (Applause.)

17 CHAIRMAN CRAWFORD: Can I ask you about  
18 one thing --

19 DR. ENIG: Sure.

20 CHAIRMAN CRAWFORD: -- I don't think  
21 you  
22 addressed directly, the deficiency of fats in the  
23 diets and their effect on skin disease? There has  
24 been some commentary about increased skin disease  
25 amongst particularly teenagers and particularly

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

[www.nealr.com](http://www.nealr.com)

1 teenage girls as perhaps being related to  
2 inadequate  
3 amounts of natural fat that you would put in the  
4 diet.

5 DR. ENIG: Right.

6 CHAIRMAN CRAWFORD: Is that valid, do  
7 you  
8 think?

9 DR. ENIG: That probably is valid, but  
10 it  
11 also may be because of an inadequate amount of  
12 Omega  
13 3 fats because the Omega 3 fats, which you should  
14 be  
15 able to find in oils like soybean oil, are missing  
16 because the Omega 3 fats are what the partial  
17 hydrogenation process gets rid of. That is the  
18 very  
19 specific way in which they end up with the  
20 stabilized  
21 fats. And they end up with very high levels of  
22 trans  
23 fatty acids.

24 I don't know how many of you realized,  
25 but

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4122

www.nealrsgross.com

1 there are studies which have shown that a lot of  
2 the  
3 trans in the foods that are coming from the big  
4 companies are 40 to 50 percent trans. So 40 to 50  
5 percent of the fats have trans fatty acids. They  
6 still have some Omega 6. And they're completely  
7 devoid of the Omega 3.

8 So you've got a complex situation where  
9 you have both an inadequate amount of things that  
10 are  
11 needed and an overwhelming amount of things that  
12 really are totally inappropriate in the diet.

13 CHAIRMAN CRAWFORD: Thank you very  
14 much.

15 DR. ENIG: Okay.

16 VICE CHAIRMAN LEVITT: Our next speaker  
17 is  
18 Sheila Cohn, Manager, Nutrition Policy from the  
19 National Restaurant Association.

20 MS. COHN: Thank you. Good afternoon.

21 My name is Sheila Cohn. I am the  
22 Manager  
23 of Nutrition Policy for the National Restaurant  
24 Association.

25 Founded in 1919, the National

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com



1 Restaurant  
2 Association is the leading business association for  
3 the restaurant industry. Together with the  
4 National  
5 Restaurant Association Educational Foundation, the  
6 association's mission is to represent, educate, and  
7 promote a rapidly growing industry that is  
8 comprised  
9 of 870,000 restaurant and food service outlets  
10 employing 11.7 million people. As such, nutrition  
11 is  
12 a priority for our ever-growing industry.

13 I would like to take this opportunity  
14 to  
15 thank the Food and Drug Administration's Obesity  
16 Working Group for giving us this opportunity to  
17 provide public testimony today.

18 We are here to suggest steps that the  
19 FDA  
20 should take to address the problem of overweight  
21 and  
22 obesity Americans. We believe that successful  
23 efforts  
24 to address this issue must focus on the foundation  
25 of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 this issue:@education.

2 Without education, the American public  
3 does not know how to incorporate the foods or the  
4 information available to them into a healthy  
5 lifestyle. If they did, the Nutrition Labeling and  
6 Education Act would have clearly impacted the  
7 significant public health issue we are discussing  
8 today.

9 For years, the American public has been  
10 provided with more choices and more information  
11 about  
12 the foods they eat than ever before, but all of  
13 this  
14 information and all of these healthy choices have  
15 not  
16 proven to be a solution and seem to have  
17 inadvertently  
18 confused consumers. We are still faced with this  
19 complex issue of obesity today.

20 It is true, however, that more  
21 Americans  
22 than in years past are aware of the important role  
23 that balance, moderation, and physical activity  
24 play  
25 in a healthy lifestyle, but we as a nation still

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 have  
2 a long way to go.

3 Many consumers are demanding more  
4 nutritious options, but there is still a great deal  
5 of  
6 the public who do not have the foundation of  
7 knowledge  
8 and the education to use the nutrition information  
9 provided to them.

10 The National Restaurant Association  
11 believes that it is important to the public to  
12 receive  
13 positive messages about nutrition from responsible  
14 officials.

15 The public is often confronted with  
16 mixed  
17 messages that they receive on nutrition. Efforts  
18 to  
19 alienate certain foods and label them as bad foods  
20 perpetuate the myth that there are good foods and  
21 bad  
22 foods.

23 Such mixed messages complicate what  
24 should  
25 be a very consistent message about healthy

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4100

www.nealrsgross.com

1 lifestyles,  
2 exercise, and personal responsibility. This is why  
3 we  
4 urge the Food and Drug Administration to provide  
5 dietary and lifestyle advice that is consistent,  
6 easily understood, and applicable to the American  
7 public today.

8           The restaurant industry's objective is  
9 to  
10 provide a variety of food options to accommodate  
11 the  
12 various needs of diverse consumers. Americans need  
13 to  
14 know that all foods can be part of a balanced diet.  
15 We believe that it is important that as the FDA  
16 examines its role and responsibilities in  
17 addressing  
18 the major public health problem of obesity, you  
19 keep  
20 in mind that our diverse population is much in need  
21 of  
22 recommendations that are understandable and  
23 relevant  
24 to how they live their lives.

25           The nutritious options are and have

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealr.com

1 always  
2 been available in the nation's restaurants. The  
3 industry's incorporating even more menu options due  
4 to  
5 increasing consumer demand in the marketplace.  
6 Today  
7 we see more diet-specific items, such as  
8 low-carbohydrate, low-fat, fiber-rich items on the  
9 menus nationwide providing options for consumers  
10 who  
11 are watching their intake of certain nutrients.

12                   Restaurants everywhere offer numerous  
13 market-driven solutions to cater to increasingly  
14 health-conscious diners, including increasing  
15 efforts  
16 to provide what their guests asked for: developing  
17 special menu items for those watching their  
18 calories  
19 and/or fat intake, providing nutritional  
20 information  
21 in brochures and on Web sites, and establishing  
22 their  
23 own initiatives to assist consumers to live a  
24 healthy  
25 lifestyle.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4100

www.nealr.com

1                   In the final analysis, we question  
2 efforts  
3 that focus solely on food or food information alone  
4 without coupling the calories in with calories out.  
5 These efforts to demonize foods or simply provide  
6 information without knowledge, understanding, and a  
7 frame of reference have failed in the past and are  
8 doomed in the future. The key is through promotion  
9 of  
10 healthy lifestyles and genuinely educating  
11 consumers.

12                   Thank you.

13                   (Applause.)

14                   CHAIRMAN CRAWFORD: When we got the  
15 Nutrition Labeling and Education Act about ten  
16 years  
17 ago, there was a lot of litany that had to do with  
18 remember, there is an E in NLEA, which you, of  
19 course,  
20 captured.

21                   And FDA was, in fact, given a charge  
22 through that act to educate the public about  
23 nutrition. I suppose it did evolve to this agency  
24 at  
25 that point in time and continues to this day.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1                   To the extent you can be brutally  
2 honest,  
3 would you say that FDA and the other agencies of  
4 government have done a good job or a mediocre job?  
5 And if you don't want to answer that, I'm not  
6 trying  
7 to put you on the spot. Is there something we  
8 could  
9 have done better categorically, not more PSA spots  
10 or  
11 something like that, but is there some kind of  
12 suggestion that could be made?

13                   I think we have tried a number of  
14 modalities, but I am not sure we have been creative  
15 enough. It strikes me as you talk about the  
16 partnerships and the knowledge that you have  
17 accumulated in the National Restaurant Association  
18 and  
19 elsewhere, you might have in secret recesses and  
20 back  
21 rooms of your organizations put forth a critique of  
22 how we could do things better. And to the extent  
23 you  
24 are willing to share that, we would appreciate it.

25                   MS. COHN: Well, I wish I had the one

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

1 answer that would solve this problem, but clearly I  
2 don't. I think one thing that is missing -- and I  
3 don't know. I don't think there is one way to do  
4 it,  
5 but I think the component that is missing with a  
6 lot  
7 of people is how to use the information provided.  
8 I  
9 don't know.

10 And a lot of people have mentioned this  
11 earlier today, where a lot of people are given this  
12 information, but they don't know how many calories  
13 they need, how much they need to expend, what they  
14 need to expend those calories. So I think that's a  
15 piece that needs to be addressed.

16 I don't think there is one way to do  
17 it.  
18 I think, as we all know, different diets work for  
19 different people. Different activity levels work  
20 for  
21 different people. So I think people need to know  
22 how  
23 to take this information and use it on an  
24 individual  
25 basis.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2724



1 CHAIRMAN CRAWFORD: Thank you.

2 MS. COHN: Thank you.

3 VICE CHAIRMAN LEVITT: Our final  
4 scheduled  
5 speaker is Dr. Maureen Storey, Director and  
6 Research  
7 Associate Professor at the Center for Food and  
8 Nutrition Policy, Virginia Tech.

9 DR. STOREY: Thank you, Joe.

10 I could be the final speaker for the  
11 day.

12 And at the risk of standing between us and rush  
13 hour  
14 traffic, I will try to be brief.

15 Thank you for this opportunity to speak  
16 on  
17 such an important issue today. I am Maureen  
18 Storey,  
19 Director of the Center for Food and Nutrition  
20 Policy  
21 of Virginia Tech in Alexandria, Virginia.

22 The center is an independent nonprofit  
23 research and education organization that is  
24 dedicated  
25 to advancing rational science-based food and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealrgross.com

1 nutrition  
2 policy. At the center, we conduct research,  
3 outreach,  
4 and other activities on current and oftentimes  
5 controversial food and nutrition policy issues.  
6 Encompassed in the center's activities on nutrition  
7 policy are its interest in policy and regulatory  
8 issues involving dietary guidance, food labels, and  
9 obesity.

10 The center recognizes the difficult but  
11 central task FDA faces when asking the question,  
12 "Based on the scientific evidence available today,  
13 what are the most important things that FDA could  
14 do  
15 that could make a significant difference in efforts  
16 to  
17 address the problem of overweight and obesity?"  
18 Therefore, the center would like to address this  
19 question with a few comments and suggestions on the  
20 very important issue of obesity in the United  
21 States.

22 In July 2003, FDA issued guidance to  
23 the  
24 industry and interim procedures for making  
25 qualified

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 health claims on human foods and dietary  
2 supplements.  
3 The center urges FDA to establish a similar  
4 rigorous  
5 framework for evaluating the weight of the evidence  
6 in  
7 forming regulations, guidances, educational  
8 campaigns,  
9 or research agendas that are within FDA's scope of  
10 responsibility in addressing the issue of  
11 overweight  
12 and obesity in the American population.

13           Undoubtedly, excess body weight is the  
14 result of an imbalance between energy consumed and  
15 energy expended. But one must be aware, too, that  
16 there are both modifiable and non-modifiable  
17 factors  
18 that contribute to one's susceptibility to becoming  
19 overweight.

20           Non-modifiable risk factors for  
21 overweight  
22 include genetics, race/ethnicity, age, and gender.  
23 For example, in various studies, African American  
24 women tend to gain more weight in the  
25 peri-menopause

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 than Caucasian women do. Also, advancing age  
2 appears  
3 to be related to increased body weight, even among  
4 healthy, active men and women.

5 Modifiable risk factors, on the other  
6 hand, are those that include lifestyle habits, such  
7 as  
8 levels of physical activity and diet. Overall,  
9 non-modifiable risk factors appear to be the  
10 strongest  
11 determinants for overweight among children and  
12 adolescents as well as adults.

13 This is not to say that modifiable  
14 factors  
15 should be ignored. Physical activity appears to be  
16 an  
17 important lifestyle component that may help prevent  
18 or  
19 at least slow unhealthy weight gain among children,  
20 adolescents, and adults.

21 In a CDC-conducted longitudinal survey  
22 of  
23 a group of 9 to 13-year-olds, 61 and a half percent  
24 did not participate in organized physical  
25 activities

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4100

www.nealr.com

1 and 22.6 percent did not participate in any  
2 physical  
3 activity during their non-school hours.

4 Physical activity is a must for all  
5 consumer communications if FDA and other federal  
6 agencies responsible for public health are to  
7 succeed  
8 in stemming rising obesity.

9 At the same time, few changes are  
10 needed  
11 to the nutrition facts panel in order to combat  
12 obesity. Again, energy expenditure must be  
13 balanced  
14 with energy intake to maintain a healthy weight.  
15 Consumers then must have the information available  
16 to  
17 properly assess caloric intake from foods consumed.

18 In response to research suggesting an  
19 important link between diet and health and,  
20 therefore,  
21 a greater demand for nutrition information on food  
22 packages, the Nutrition Labeling and Education Act  
23 of  
24 1990 mandated that nearly all FDA-regulated food  
25 packages display nutrient content, including

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 calorie  
2 content, per serving of food.

3 Information, however, does not  
4 necessarily  
5 mean that consumers will have the education to make  
6 healthy decisions or even choose to do so. Thus,  
7 nutrition education is a necessity.

8 In closing, the center urges FDA to use  
9 an  
10 evidence-based evaluation of the currently  
11 available  
12 science to determine the most important factors in  
13 development of overweight and obesity; develop a  
14 framework to address the issues within the scope of  
15 FDA's mission and responsibility; establish and  
16 amend  
17 regulations based on the strength of the evidence;  
18 begin an education campaign that helps consumers  
19 understand the nutrition label; and collaborate  
20 with  
21 the Department of Education to institute  
22 age-appropriate nutrition education curricula in  
23 elementary, middle, and high schools.

24 Thank you very much for your time. I  
25 hope

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealrsgross.com

1 these comments have been useful.

2 (Applause.)

3 CHAIRMAN CRAWFORD: The education part  
4 that you mentioned is a big undertaking.

5 DR. STOREY: Yes, it is.

6 CHAIRMAN CRAWFORD: I thought I grasped  
7 in  
8 your comments the question of scientific literacy  
9 or  
10 nutritional literacy. Is there a base that's  
11 sufficient in the American population that could  
12 deal  
13 with this or do we need to start in the schools or  
14 something like that?

15 I don't mean to be maudlin about it,  
16 but  
17 when we put in the NLEA ten years ago, we thought  
18 that  
19 that would be sufficient, that everybody would wind  
20 up  
21 being svelte, beautiful, energetic, and never have  
22 to  
23 do anything else. That clearly hasn't helped with  
24 this particular problem.

25 Do you have comments on there? Is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1       there  
2       a way to get at it? I am not trying to put you on  
3       the  
4       spot, but you need to be put on the spot.

5                   DR. STOREY: NLEA was a beginning. And  
6       I  
7       think that stemming the obesity epidemic, if you  
8       want  
9       to call it that, is going to be a long, slow,  
10      unattractive process. I think we have to begin in  
11      the  
12      schools so that every eighth grade graduate knows  
13      how  
14      to use math so that they can calculate calories in  
15      a  
16      serving of food.

17                   Without that, I think that we are  
18      doomed  
19      to failure, that we can label as much as we want,  
20      but  
21      if people don't know how to use the information and  
22      do  
23      a simple multiplication of how many calories are in  
24      a  
25      serving of food, we are not going to succeed, no

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com



1 matter what the federal government does.

2 CHAIRMAN CRAWFORD: Thank you.

3 VICE CHAIRMAN LEVITT: Before I turn it  
4 over to Dr. Crawford to close the meeting, you note  
5 we  
6 do have microphones on each aisle. Is there  
7 anybody  
8 in the audience who was not a scheduled speaker who  
9 would like to make a brief comment? If there is  
10 one,  
11 just please come up and stand up at the microphone  
12 and  
13 please identify yourself.

14 OPEN DISCUSSION

15 MR. CAMPBELL: Hi. My name is Doug  
16 Campbell. I am not speaking on behalf of a client  
17 but  
18 as one who perhaps weighed too much as a child.

19 My question, my comment is -- and I did  
20 not hear the morning's proceedings. I only came in  
21 after lunch. Nobody here has addressed to me what  
22 is  
23 maybe the most critical factor, which is why do  
24 people  
25 eat more than they should? Why do people eat when

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

1 they feel full and, in particular, children?

2           It seems to me a lot can be done that  
3 is  
4 useful and productive in terms of educating people  
5 and  
6 giving them more information, but if they are  
7 driven  
8 by other factors outside of what we would consider  
9 rational food choices or rational activity choices,  
10 then we're going to be whistling into the wind to  
11 some  
12 extent, regardless of what we do.

13           And as long as we're talking research,  
14 as  
15 long as we're talking finding what really has to be  
16 done in order to turn this trend around, why not  
17 look  
18 at those causes? They may not be susceptible to  
19 much  
20 change by the Food and Drug Administration. But to  
21 ignore them, it seems to me, really handicaps us in  
22 any march towards a successful resolution.

23           VICE CHAIRMAN LEVITT: Thank you for  
24 that  
25 comment. Good suggestion.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 Yes, over here?

2 MS. DAVIS: Hello. My name is Tezima  
3 Davis. I am with the Food and Nutrition Board of  
4 the  
5 Institute of Medicine.

6 I wanted to bring up two related issues  
7 that I think are pretty important. One is the  
8 culturally appropriate messages. A lot of people  
9 mentioned talking about messages that actually  
10 work,  
11 and one aspect of that is having culturally  
12 appropriate messages.

13 And then the tie-in with that is health  
14 care disparities because, as one of our Institute  
15 of  
16 Medicine reports discussed, the very people who are  
17 least likely to get health care are those who are  
18 suffering the most from this obesity issue.

19 So not only the culturally appropriate  
20 messages but also recognizing that people who don't  
21 have health care or are under-insured or anything  
22 of  
23 that nature may not be getting these messages, and  
24 also the messages may not be as easily accessible.

25 I've heard a couple of the speakers

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4422

www.nealr.com

1 mention that you can just go on the internet.  
2 Well,  
3 these same people might not have internet access or  
4 simply one hour a day to look for information for  
5 their entire family with that one hour at a public  
6 library. This can pose significant issues for them  
7 acquiring just the information that we're talking  
8 about here today.

9                   So I just hope that in your  
10 deliberations,  
11 you can discuss and try to come up with some  
12 solutions  
13 for these issues. Thanks.

14                   VICE CHAIRMAN LEVITT: Thank you.

15                   Over here?

16                   MR. BARKIN: My name is David Barkin.

17 I  
18 am speaking for myself, not my company.

19                   I have a David Letterman-type solution,  
20 which is the more you weigh, the more you should  
21 have  
22 to pay for food. It should be built right into  
23 your  
24 credit card so you swipe it there at the cash  
25 register. And if you're, say, over BMI of 35, that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

1 candy bar should be \$5.

2 More seriously, as someone who follows  
3 the  
4 exercise literature, bicycles about 3,000 miles a  
5 year, and still has a BMI of 30, I don't think  
6 exercise is going to be the panacea.

7 I think it takes about 400 calories per  
8 day of exercise to help maintain a constant weight.  
9 So it's not as easy. It's not going to be the easy  
10 explanation for getting people to exercise more and  
11 counterbalance that, say, 100 extra calories there  
12 of  
13 food. There's not an equivalency there. It just  
14 takes a lot more exercise than most of us have time  
15 for to make that the only solution.

16 Thank you.

17 VICE CHAIRMAN LEVITT: Thank you.

18 Anybody else? Looking around.

19 (No response.)

20 VICE CHAIRMAN LEVITT: With that, I  
21 will  
22 turn the microphone back to Dr. Crawford.

23 CHAIRMAN CRAWFORD: Thank you very  
24 much,  
25 Joe, and I appreciate your moderation of the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4422

www.nealr.com

1 program.

2 CONCLUSION AND NEXT STEPS

3 CHAIRMAN CRAWFORD: To all of you who  
4 attended this meeting and all of you who made  
5 testimony, let me just close by saying how much the  
6 Food and Drug Administration and HHS appreciate  
7 those  
8 inputs.

9 We can assure you that what you say  
10 will  
11 be memorialized, as they say, in stage, screen,  
12 radio,  
13 and everywhere else. Even as we speak, this  
14 particular program is being Webcast. As I  
15 mentioned  
16 earlier, it's being archived. I don't want anyone  
17 to  
18 leave here thinking that your efforts will be lost  
19 in  
20 the midst of time.

21 They are going to be memorialized. And  
22 there will be a comprehensive report delivered by  
23 this  
24 task force that we mentioned earlier at FDA on  
25 time.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-0704

(202) 331-4400

www.nealrsgross.com

1 And one of the appendices will include your  
2 reports.

3 The other thing is that I think we have  
4 to  
5 acknowledge that we came today, we saw, we heard,  
6 but  
7 we did not conquer. We still have a hideous  
8 monster  
9 out there that is one of the major public health  
10 problems in the making that we have ever had in  
11 this  
12 country. And it is something that we are all  
13 obligated to deal with and do something about in a  
14 creative and productive way.

15 So we are going to be in constant  
16 contact,  
17 you and us and everyone else who has a stake in  
18 this,  
19 which is everything that moves and walks upon the  
20 Earth, particularly in the United States of  
21 America.

22 So best to all of you. To you who have  
23 come from other cities and so forth, safe travels  
24 home. Please stay in touch with the FDA. And also  
25 let us know as you reflect on what happened today

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704

(202) 331-4400

www.nealrsgross.com

1 anything that you think comes to your mind. Do it  
2 in  
3 the form of a petition, a letter, or comments on  
4 this  
5 meeting. Let us hear from you.

6 And thanks again very much indeed.

7 (Whereupon, at 4:35 p.m., the foregoing  
8 matter was adjourned.)

9  
10  
11  
12  
13  
14  
15

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-2704