EXECUTIVE SUMMARY

Obesity has risen to epidemic levels in the U.S. It leads to devastating and costly health problems, reduces life expectancy, and is associated with stigma and discrimination. Obesity is a strong risk factor for such serious diseases as type 2 diabetes and heart disease; it is also a risk factor for certain cancers and is associated with depression and other medical conditions. More than 65 percent of U.S. adults are overweight or obese, with nearly 31 percent of adults—over 61 million people—meeting criteria for obesity. Furthermore, while obesity and overweight have risen in the population in general, the greatest increases observed over approximately the past two decades have been in the prevalence of extreme obesity; those who are severely obese are most at risk for serious health problems. Levels of childhood overweight have nearly tripled since 1970: approximately 16 percent of children and teens ages 6 through 19 are now overweight. The levels of pediatric overweight have ominous implications for the development of serious diseases, both during youth and later in adulthood. Overweight and obesity also disproportionately affect racial and ethnic minority populations, and those of lower socioeconomic status. Left unabated, the escalating rates of obesity in the U.S. population will place a severe burden on the Nation's health and its healthcare system.

Obesity and NIH Research

On the surface, it may seem that the solution to the obesity epidemic is obvious: "Get people to eat less and exercise more." The reality is that this change is very difficult to accomplish, and research is critical to address the issue successfully. Given the complexity and multiplicity of the forces driving the obesity epidemic, the NIH recognizes that it cannot, by itself, solve this major public health problem. However, the NIH can and must be a key contributor to solving the obesity problem through scientific research. Through its research mission, the NIH is seeking to capitalize on recent scientific discoveries to propel new efforts toward further understanding the forces contributing to obesity and toward developing strategies for its prevention and treatment.

The increase in obesity has been fueled by a complex interplay of environmental, social, economic, and behavioral factors, acting on a background of genetic susceptibility. Thus, the NIH supports a broad spectrum of obesity-related research, including molecular, genetic, behavioral, environmental, clinical, and epidemiologic studies. The challenges of today's obesity epidemic are daunting, yet the discoveries emanating from previous research investments offer unprecedented opportunities for new scientific research efforts to help meet these challenges.

NIH Obesity Research Task Force

Given the importance of the obesity epidemic as a public health problem, and its relevance to the mission of most of the NIH Institutes, Centers, and Offices (ICs), the NIH Director Dr. Elias Zerhouni established the NIH Obesity Research Task Force in April 2003, as a new effort to accelerate progress in obesity research across the NIH. The Task Force is co-chaired by the Director of the National Institute of Diabetes and

Digestive and Kidney Diseases (NIDDK), Dr. Allen M. Spiegel, and by the Acting Director of the National Heart, Lung, and Blood Institute (NHLBI), Dr. Barbara Alving. The members of the Task Force are representatives from these institutes and many other NIH components with relevant expertise. A key element of the NIH Director's charge to the Task Force is the development of a Strategic Plan for NIH Obesity Research.

The Strategic Plan for NIH Obesity Research: Informing the Process

Purpose and Formulation of the Strategic Plan

The purpose of the Strategic Plan for NIH Obesity Research is to provide a guide for coordinating obesity research activities across the NIH and for enhancing the development of new research efforts based on identification of areas of greatest scientific opportunity and challenge. The Strategic Plan represents a cohesive, multi-dimensional research agenda for addressing the problem of obesity. It includes short-, intermediate-, and long-term goals for basic, clinical, and populationbased obesity research, along with strategies for achieving those goals that also range in timeframe. Building on scientific advances from previous NIHsupported efforts, the Strategic Plan seeks to maximize collaboration among the NIH ICs and capitalize on their expertise and interest in developing obesity research initiatives.

Importantly, the planning process was informed by input from external experts through interactions with NIH staff at scientific meetings, through meetings and workshops convened by NIH ICs for the purpose of obtaining research planning advice, and through presentations by the Co-chairs of the Task Force to external scientific and health advocacy organizations. For example, a "Think Tank" meeting on enhancing obesity research, held by the NHLBI, brought together a diverse group of stakeholders from the academic, consumer, and professional communities to provide research recommendations. Recent general scientific meetings offered a venue for NIH staff to glean external input and advice on obesity research planning. For example, a January 2003 Keystone meeting provided a means of tapping external scientific expertise regarding the pathogenesis and treatment of obesity. Later in 2003, the Co-chairs of the NIH Obesity Research Task Force gave the keynote lecture at the

Annual Scientific Meeting of the North American Association for the Study of Obesity (NAASO); this presentation afforded an opportunity to gain feedback from attendees on NIH obesity research efforts. An important advisory group from whom the NIH receives expert input on obesity is the NIDDK Clinical Obesity Research Panel (CORP), which is composed of leading external obesity researchers and clinicians. Additionally, strategies designed to achieve the goals of the Plan, in the form of initiatives, are reviewed and discussed by members of the ICs' National Advisory Councils, which are groups of prominent external scientific experts and lay leaders established by law and charter to provide advice to the ICs.

In addition to the external advice that the NIH receives through the avenues above, which continues to inform the obesity research planning process, the Strategic Plan document was circulated in draft form to invite comments from over 70 external individuals, including scientists with expertise in obesity research and leaders of voluntary and professional health advocacy organizations who could provide comments on behalf of these organizations. After receiving input from this effort (from nearly half of the individuals to whom NIH sent the draft, as well as from others with whom some of those individuals shared the draft), the revised Draft Strategic Plan for NIH Obesity Research was posted on the Internet to invite further scientific and public comment before production of a final version, which incorporates suggestions received during the final comment period.

The Strategic Plan is focused on research efforts that are funded by the NIH, specifically, those initiated by the NIH. Extramurally, the NIH supports both investigator-initiated research projects and research that results from NIH-initiated efforts—solicitations for grant applications and contract proposals. Although investigator-initiated research (projects proposed by individual scientists in areas that they identify) represents a substantial portion of the NIH funding portfolio and will continue to receive vigorous support in the future, it is not the intent of the Strategic Plan to cover the vast array of these studies. The NIH also supports an Intramural Research Program, which provides a unique resource for obesity research.

Through consultative efforts such as those described above, the NIH seeks to encourage investigators to apply their expertise toward: developing studies in areas of particular scientific opportunity or interest; addressing gaps in knowledge identified by the scientific community; overcoming barriers to advance research or to translate research results into public health and clinical practice; or pursuing other areas of research critical to the mission of the NIH.

A Dynamic Planning Process

As with any future-oriented plan, the Strategic Plan for NIH Obesity Research is intended to be dynamic. As new scientific opportunities arise from current research investments and accomplishments, the research planning process will evolve to build on these areas, thus accelerating research in the most promising directions to continue to meet the challenges of obesity.

Strategic Plan for NIH Obesity Research: Goals for NIH Obesity Research, and Strategies for Achieving the Goals

The Strategic Plan contains a cohesive set of interrelated goals for achievements in NIH obesity research. The goals are organized under the following four themes:

- Research toward preventing and treating obesity through lifestyle modification.
- Research toward preventing and treating obesity through pharmacologic, surgical, or other medical approaches.
- ▶ Research toward breaking the link between obesity and its associated health conditions.
- Cross-cutting research topics, including health disparities, technology, fostering of multidisciplinary and interdisciplinary research teams, investigator training, translational research, and education/ outreach efforts.

For each of these four themes, goals for the short-, intermediate-, and long-term time horizons are presented, followed by a set of strategies for achieving the goals:

Research toward preventing and treating obesity through lifestyle modification.

Under this theme, the goals and strategies for achieving them encompass identifying modifiable behavioral and environmental factors that contribute to the development of obesity in children and adults, and designing and testing potential intervention strategies. Research will build on the results of clinical trials that demonstrated successful behavioral and environmental approaches to lifestyle modification. The effects of specific modifications in diet and physical activity will be studied, as will modifications of environmental factors that promote over-consumption of food and sedentary lifestyles. Two examples of such research are work-site interventions to prevent obesity and studies of the "built environment" and its relationship to physical activity.

Research toward preventing and treating obesity through pharmacologic, surgical, or other medical approaches.

Under this theme, the goals and strategies for achieving them encompass the continued elucidation of the molecules and biological pathways that regulate appetite, energy expenditure, and the storage of energy as fat; and accelerating the design and testing of treatment and prevention strategies. Research will include further genetic and other molecular studies. With respect to genetic research, some individuals are far more susceptible to developing obesity in a given environment than others. In rare cases of severe, early-onset obesity, this susceptibility results from a single genetic abnormality. Yet, more common forms of obesity are genetically complex, likely involving interactions of variations in multiple genes to increase susceptibility. The identification of genes involved in obesity will enhance efforts toward prevention and treatment. Through genetic studies and other molecular research, the NIH can identify potential new targets for drug development. These "targets"

- would be the molecules and pathways involved in regulating energy balance—the balance between energy intake (through feeding) and energy expenditure (through physical activity and maintaining basic body functioning). Thus, research in these areas will contribute to the development of medical strategies that affect energy balance to help prevent or treat obesity.
- Research toward breaking the link between obesity and its associated health conditions. Under this theme, the goals and strategies for achieving the goals encompass building on research that illuminates the connection between obesity and type 2 diabetes, cardiovascular disease, cancer, and other diseases. Major recent advances in the understanding of fat cell metabolism include the appreciation that fat cells secrete hormones that promote inflammation and hypertension. Understanding the different mechanisms of various body fat depots in causing insulin resistance (a precursor to diabetes) and other metabolic abnormalities is a fundamental question that must be addressed. Such research efforts as the recent creation of a bariatric surgery clinical research consortium and the formation of a network to study nonalcoholic fatty liver disease (a major new cause of liver failure associated with the obesity epidemic) will help to identify the mechanisms linking obesity to other serious health conditions, and will open the possibility of breaking the link between them.
- Cross-cutting research topics, including health disparities, technology, fostering of multidisciplinary and interdisciplinary research teams and investigator training, translational research, and education/outreach efforts.
 - The cross-cutting research theme encompasses several topics. First, of critical importance is a focus on the needs of specific populations, including children, racial/ethnic minorities who are disproportionately affected by obesity, persons living in conditions of lower socioeconomic status or who have low literacy, women, older adults, those with disabilities, and those who are extremely obese. For these special populations, goals and strategies to achieve the goals are found throughout the Strategic Plan as an integral part of obesity research. For example, the Strategic Plan includes a number of initiatives focused on childhood obesity, such as prevention in the pediatric primary care setting, and a multi-pronged school-based prevention trial. Because of the large racial/ethnic disparities in the incidence of obesity, a number of the efforts described in the Plan are directed at understanding the biologic and environmental factors contributing to such disparities and to addressing them in a culturally-sensitive manner. Also relevant to health disparities is communication of the results of scientific research. The Plan addresses the importance of tailoring education and informational efforts to different populations in culturally appropriate ways that provide effective communication.

Another cross-cutting area is fostering multidisciplinary and interdisciplinary research teams. Although the first two themes—on research toward preventing and treating obesity through lifestyle approaches and medical approaches are listed separately, they are, in fact, interdependent. Effectively addressing the obesity epidemic will require the NIH to bridge the study of the behavioral/environmental causes of obesity and the study of the genetic/biologic causes. Ultimately, the NIH seeks to create a new interdisciplinary approach in which behavioral/lifestyle interventions are informed by a deeper understanding of the biologic and genetic factors, and vice versa. Successful prevention and treatment of obesity may well require combined medical and behavioral approaches in highly susceptible individuals. Given the multi-dimensional nature of the obesity epidemic, research efforts need to engage those with expertise in a variety of other areas, including, for example, economics, and fields relevant to the built environment and community design.

Translational research—progressing from basic science to clinical studies and from clinical trial results to community interventions—is another key cross-cutting research topic. For example, the NIH will study the effects of "social experiments" such as recent policy decisions in some schools concerning food offerings made available to the students. By obtaining data on the outcome of such policy decisions, the NIH can help policy makers develop further actions based on data rather than on assumptions.

To continue to advance progress in many obesity research areas, efforts to improve technologies will be valuable, as will efforts addressing the availability of resources for research. The NIH plans, for example, to encourage research to improve technologies for studying dietary intake and physical activity.

Finally, the NIH will continue activities to disseminate the results of research to the public and healthcare providers. It will be important that clear and appropriate communication, including messages and information about healthy eating, physical activity, and weight control strategies, reaches diverse audiences.

As noted in the Strategic Plan, the NIH will also partner with other agencies in the Department of Health and Human Services (HHS), other government departments, organizations in the private sector, and foundations and other public groups. By bringing data derived from rigorously reviewed and conducted studies to its partners, the NIH can contribute to framing the actions to address the obesity epidemic.

NIH Obesity Research Task Force Web Site

As one component of NIH efforts to enhance research on the major public health problem of obesity, the NIH Obesity Research Task Force has developed a new Web site (http://obesityresearch.nih.gov/). The primary purposes of this Web site are to help inform investigators about NIH funding opportunities for obesity research, to provide information on NIH-sponsored scientific meetings relevant to obesity, and to provide other information relevant to obesity research. In providing this information, the Web site will reflect the dynamic and ongoing planning process for obesity research at the NIH. Additionally, the Strategic Plan for NIH Obesity Research was posted on the Web site in draft form—after having

already received substantial external input—in order to invite further scientific and public comment before publication of the Plan. Finally, although the focus of the Web site is on research, the site also includes links to other NIH Web sites that provide information to the public and health professionals on weight loss, nutrition, physical activity, and health problems associated with obesity.

Through the collective efforts of the NIH Obesity Research Task Force—and the ICs they represent—the NIH will strive to bolster obesity research to improve public health.