



The direct costs of obesity (\$51.6 billion; 1995).

promote research into the genetic determinants of obesity, to search for viable preventative measures, to improve cooperation between different areas of obesity research and to expand the training of new investigators in the field. But although the group updated Varmus on the latest obesity findings and emphasized the need to determine the direction that science must take to tackle the fat issue, funding details have not been forthcoming. "Varmus has made no commitment to a research initiative as yet, but we are hoping that more resources will be allocated," Eckel told *Nature Medicine*.

According to Karen Donato, coordinator of the NHLBI Obesity Education Initiative, the main impetus for drawing up the clinical guidelines on obesity is the ever-increasing amount of pharmaceutical research dedicated to weight loss medicines and the growing number of new

diet drugs on, or approaching, the market. "With new pharmacotherapies available, there will have to be a number of clear guidelines for physicians about who is overweight and who should get these drugs," says Donato. The American public spends around \$33 billion on diet products and services each year.

Although the NHLBI has issued previous guidelines on cholesterol and blood pressure values that have included obesity figures, the institute has never before focused on the issue of obesity *per se*. The new guidelines were created by a 24 member panel of primary care physicians, obesity researchers, nutritionists and exercise and behavior modification experts.

"We wanted to help health care providers evaluate a patient's weight status in relation to other health factors, and give them the tools to deal with weight issues," explains Donato. "The document is an evidence-based model of what happens to lipids, glucose and blood pressure when patients are overweight, and how obesity can lead to other diseases." Excessive weight increases the risk of hypertension, lipid disorders, coronary heart disease, type II diabetes, gallbladder disease, stroke, osteoarthritis, certain cancers and sleep apnea. A recent study estimates that diseases directly associated with obesity cost \$51.6 billion per year and indirect costs, including lost work days, are

equivalent to those associated with cigarette smoking (\$47.56 billion) (*Obes. Res.* 6; 97, 1998).

Susan Yanovski, director of the obesity and eating disorders program at the NIDDK says that the prevalence of obesity has increased dramatically in the past decade. The guidelines reveal that most of the American population—55 percent—is now overweight, while 22 percent is clinically obese. "There has been an especially large increase in the higher levels of overweight people—people that are 40–50 pounds overweight," adds Yanovski.

The guidelines also provide some explanation as to why the number of obese Americans has skyrocketed over the last decade—"we're a lot more sedentary now than we once were," says Donato. "Also, since people are eating low-fat foods, they think it's OK to eat more."

The guidelines instruct physicians to assess a patient's risk by assessing body mass index (BMI), waist circumference and other obesity risk factors, such as high blood pressure or a family history of obesity-related disease. And the definition of obesity has been redefined. "If a patient has a BMI of 25 to 29.9, the physician should recommend his patient to not gain any weight, but if he also has two risk factors, the patient would need to lose weight," says Donato.

KRISTINE NOVAK, NEW YORK

HIV vaccines—and the winner is...

Donald Francis has prevailed. He has succeeded in moving his company's gp120 HIV envelope protein vaccine (Aidsvax) into Phase III clinical trials—making it the most advanced vaccine worldwide in terms of clinical development—despite repeated warnings by many of the most senior AIDS researchers in the US that the vaccine will not work.

Francis, president of the South San Francisco, California biotechnology company VaxGen, received Food and Drug Administration (FDA) approval for trials in high risk volunteers in the US (5,000) and Thailand (2,500) last month. The news comes four years after the director of the National Institutes of Allergy and Infectious Diseases, Anthony Fauci, refused to support the vaccine based on its low efficacy in eliciting an antibody and cytotoxic T-cell response.

In the months following this decision, VaxGen was spun off as a separate company from the originators of the gp120

vaccine, Genentech, and Francis courted private investors to finance future development of Aidsvax.

Questions about the vaccine's effectiveness surfaced again earlier this year with the publication of a research paper that showed breakthrough infections following inoculation of 18 subjects (*J. Virol.* 72; 1552, 1998). The vaccine was no better than control in preventing HIV infection.

However, Francis and other Aidsvax supporters argue that Phase I–II studies are not designed to demonstrate efficacy and that statistical criticisms of the rate of infection calculations can only be properly addressed using the sample size that Phase III testing allows. Whether it proves efficacious in large scale

testing or whether it turns out to be a waste of time, money and volunteer resources will be known in another four years.

The issue of whether or not any of the HIV vaccines currently in development are suitable for advance into large clinical trials has been fiercely debated for many years (*Nature Med.* 4; 648, 1998; 1; 1105, 1995). Although empiricists, who have insisted that widespread testing is the only way to move forward, will feel vindicated by the FDA's decision,

basic scientists are left to cling to the silver lining on what they view as the gp120 cloud: that the trial will at least get this vaccine approach out of the system.

KAREN BIRMINGHAM, NEW YORK

IMAGE
UNAVAILABLE
FOR COPYRIGHT
REASONS