Thank you very much. I am pleased to be a part of this important symposium on the crisis in clinical research and in particular to highlight the role that the US Department of Agriculture (USDA) plays in clinical research. We are actively engaged in clinical research with a focus on the disease prevention side rather than the treatment side. Today, I will introduce you to our program and share some examples of real-world outcomes and impacts of our clinical research.

**Clinical Research in the USDA**

Most people do not recognize that the USDA conducts clinical research. There are 2 agencies within the USDA engaged in clinical research: the Agriculture Research Service (ARS), where I work, and our sister agency, the Cooperative State Research Education and Extension Service, now known as the National Institutes of Food and Agriculture. The ARS has the in-house portion of the research program, and the National Institutes of Food and Agriculture has the extramural or competitive-grants portion of the research. Both agencies conduct clinical research examining the role that foods, nutrition, and physical activity play in preventing human disease. Information on the ARS human nutrition research program is available at www.ars.usda.gov/HumanNutrition.

The total ARS budget is $1.14 billion, and 7% or about $85 million is devoted to human nutrition research. Because ARS is an intramural agency, the budget funds salaries, building maintenance, and other overhead expenses in addition to direct research costs. The Cooperative State Research Education and Extension Service has a $1.2-billion budget, with approximately $15 million for nutrition research. Their budget funds research on bioactive food components and prevention of obesity. This presentation will focus on the ARS Human Nutrition Research Program where most of USDA’s clinical research is conducted.

**Clinical Research in the ARS**

In ARS, our research focus is in 2 areas: dietary requirements to promote health from pregnancy through old age, and prevention of obesity and chronic diseases through nutrition and lifestyle-based approaches. Most of our clinical research is conducted with volunteers at 6 human-nutrition research centers located throughout the United States. These locations provide access to the diverse American population in urban and rural settings, from most racial and ethnic groups, and from all age categories, including children and the elderly. Three centers—in Davis, CA; Grand Forks, ND; and Beltsville, MD—are federal centers where the scientists receive much of their research money from the USDA. These 3 centers focus primarily on research with adults.

On the other hand, the 3 centers in Houston, TX; Little Rock, AR; and Boston, MA, are what we call our collaborating centers. In these locations, we conduct research in collaboration with local universities. In Houston, the USDA’s Children’s Nutrition Research Center collaborates with the Baylor College of Medicine. In Boston, we collaborate with Tufts University. The centers in Houston and Little Rock focus on the nutritional needs of children, and the Boston center addresses the nutritional needs of aging adults. Through clinical research at these centers, we research the full lifespan.

Our clinical research centers have specialized facilities for controlled human nutrition research—metabolic kitchens to prepare nutritionally precise meals/snacks for children and adults, dining facilities to carefully monitor food consumption during studies, and laboratories for controlled exercise, biological specimen collections, and body composition measurements (Fig. 1). In most studies, we provide meals—breakfast, lunch, and dinner—and snacks rather than providing nutrients in a capsule. We collect various types of biological samples, such as blood, 24-hour urines, and biopsies of adipose tissue. We also focus research on physical activity and conduct energy expenditure and other activity-related tests (Fig. 2). The centers have state-of-the-art equipment for measuring body composition, such as the dual energy x-ray absorptiometry (DXA) machine or the BOD POD (Life Measurement, Inc, Concord, Calif) for use with adults and children. All locations use “omics” tools to understand how diet and physical activity can prevent disease, and 2 of the centers have equipment for metabolomics—many metabolites in the blood vary with dietary patterns and genotypes. Understanding these relationships can assist in predicting the risk of chronic disease. We conduct both residential and free-living studies at the clinical research centers of varying duration: a few days to a few months. Increasingly, we are less able to conduct residential studies because of high costs.

**Research Accomplishments From the ARS**

Some selected research accomplishments follow to show the breadth of clinical research at USDA.

Plant breeders produced carrots of varying colors (Fig. 3), which were then tested in clinical research studies to determine the human bioavailability and health-promoting effects of the bioactive pigment components. The researchers studied what pigments are beneficial to humans and the extent to which they are absorbed and metabolized. One such compound studied was beta-carotene, the orange pigment in carrots and other foods that is converted to vitamin A in the human body. This information was used to determine the appropriate foods and the amounts of...
those foods needed to provide sustainable solutions to vitamin A deficiency in developing countries.

Agriculture Research Service scientists conducted the early research on dietary trans fatty acids and their adverse effects on human health. Conducted under carefully controlled conditions at our clinical research center in Beltsville, MD, this research showed that consumption of trans fatty acids results in increased low-density lipoprotein (LDL) cholesterol, a primary risk factor for cardiovascular disease. The research resulted in new mandatory FDA food labeling requirements for trans fats.

The ARS has done and continues to conduct considerable research on nutrient requirements for children, adults, and the elderly. In fact, we provide most of the research used to establish the nutritional standards for the United States, and now also for Canada, because the United States and Canada are working together in this area.

**THE IMPACT OF OUR CLINICAL RESEARCH**

Agriculture Research Service research contributes much of the science base for the United States–recommended and Canadian-recommended nutrient standards developed by the National Academies’ Institute of Medicine and for the food intake recommendations in the USDA/Department of Health and Human Services Dietary Guidelines for Americans. The Dietary Guidelines for Americans form the basis for Federal nutrition policy and undergird USDA’s nutrition assistance programs, the food safety net in the United States (Fig. 4). This information is used in the nutrition-facts label on food packages to inform consumers.
consumers, and it also feeds into the USDA's MyPyramid food guidance system by which the USDA disseminates nutrition information to the American public. Thus, the impact of this clinical research is far reaching and contributes in meaningful ways to improving the health of the US population.

What does the USDA need to be more successful in clinical research? Our concerns are very similar to those mentioned by other speakers in this symposium. Our research budget has not kept up with inflation over the last decade, and the lack of funding increases has already eroded our ability to conduct clinical research. We are also very concerned with unfunded building and infrastructure problems, and a sizeable percentage of the intramural scientists and staff at our centers—those who are conducting this research—are nearing retirement. We wonder if we will have investigators with appropriate training to continue this kind of clinical research in the future. We wonder if we will be able to attract new investigators because our salaries are not as competitive as other fields for highly educated people. These problems, which are impacting all clinical researchers and clinical research institutions, are impacting the USDA as well.

**FIGURE 4.** Nutrient requirements for children, adults, and older persons.