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HIDDEN HUNGER: THE ROLE OF NUTRITION, FORTIFICATION, AND BIOFORTIFICATION

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Thank you and good afternoon, everyone. As Catherine Bertini told you, I'm here actually in two capacities. One is as Dean of Agriculture at Iowa State University, and on behalf of all of the students and faculty within the College of Agriculture, we want to extend to you, Catherine, and to all the returning laureates – Welcome home to Iowa. And particularly we want to extend our congratulations to Professor Yuan Longping and also to Dr. Monty Jones.

The second capacity in which I am here is as the chair of the Food and Nutrition Board, and it's from the work that we have been doing, particularly over this last decade, that I have framed my comments today.

The central question that human nutrition scientists have been addressing as long as we've been trying to figure out how food relates to health is – what substances in food and in what amounts are necessary for good health?

The science of nutrition developed some endpoints that we used to assess good health and used them very well over a period of about fifty years, to define what are the range of the central nutrients, and those traditional endpoints are shown here (referring to PowerPoint): Growth and development in infants, youth and children; successful reproduction; and also the prevention of what we've come to call the deficiency diseases – scurvy, beriberi and others.

But also, particularly over this last fifty years, we've had an intense debate that's gone on within the nutrition community about – What else should we be considering with respect to how food relates to health? So we've been addressing the question of – What constitutes good health? So the question is – What else constitutes good health?

We've relied very heavily on our colleagues in epidemiology and in the biomedical community to, through observational studies as well as clinical trials, determine what other array of substances in food relate to the risk of chronic diseases of aging. We've also relied on that type of investigative approach to help to define what role the essential nutrients may also play in contributing or to mitigating the risk of these chronic diseases of aging. These include things like Type 2 diabetes and cardiovascular disease and several other common diseases of aging.

More recently, research in epidemiology has come together with ongoing research on how substances in food affect gene expression to define a new concept that's gaining greater currency that relates to exposures during early development, either fetal development or early in life, and how those exposures to nutrients and other substances in food affect the later health risks in particularly these chronic diseases.

What has occurred then in the scientific community, and particularly in the nutrition science community is that this body of research has led us to expand the number of endpoints that we use for defining what constitutes good health. So in addition to the three that we have traditionally used – growth and development, successful reproduction, and prevention of deficiency disease – we've added onto that, prevention of the chronic diseases of aging, prevention of toxicity and other adverse effects that may occur with very high levels of intake of specific nutrients, as well as the maintenance of physiologic functions that are very important, things like bowel function or immune function.

We have also expanded the number of nutrients for which we're able to make recommendations about a level of intake that's consonant with good health. Sixty years ago the U.S. Government came to the National Academy of Sciences and asked for the Academy's advice about how to plan diets for the American population during World War II. There was concern about the availability of sufficient food to promote and maintain the good health in our population. The Food and Nutrition Board conducted its first study of what was known about human nutrient requirements and formulated the first set of recommended dietary allowances in response to that request from the government.

Recommendations were made for energy and protein of two minerals, calcium and iron, and for six vitamins. Fifty years later, in 1989, after what had been a half century of enormously productive scientific research on nutrient requirements, the Food and Nutrition Board issued the tenth version of the recommended dietary allowances in which recommendations were made for energy and protein, but the number of mineral elements for which recommendations were made had increased to seven, the number of vitamins for which recommendations were made had increased to eleven; and in addition the board made recommendations for seven other nutrients for which there wasn't a sufficiently rigorous scientific base to set a recommended dietary allowance but for which we knew enough to provide recommendations on what would constitute a safe and adequate level of intake.

The recommendations up until that time, the review had been done on about a five-year basis, and in 1994 the board took up again the question of reconsidering what should we do about these recommended dietary allowances. And the board at that time had a whole series of different issues that they felt needed to have a board discussion within the scientific community and issued a paper in 1994 to eventually disspark that debate. The paper raised questions about the fact that the recommendations over the fifty years in which they had been used had broadened with respect to the numbers of applications that were being made of them. What had begun originally as recommendations for planning the procurement of foods and the planning of meals for populations were being used to label foods or to formulate dietary supplements. In addition, these recommendations were being applied to individuals, although in concept they had been developed only for use in populations.

Also during this fifty-year period of time, we'd come to learn an enormous amount about how these nutrients, as well as other substances in food, were affecting the risk of chronic diseases. And the board put out the question – Should chronic disease prevention endpoints be included in the formulation of these dietary recommendations?

We also were learning that there were a lot of other substances in food that had bioactive effects. And the question was – even though they did not fit the definition of a nutrient, should those also be included? We were interested in having an open dialog with interested groups and were also concerned about the extensive fortification of the U.S. food supply as well as the amount of self-prescription of supplementation that was going on without a good understanding of what constituted an upper safe level for intake of nutrients and questioned whether we should be establishing that upper level of intake as well.

What the end of that consultation was, was a series of in-depth studies that were conducted by the Food and Nutrition Board over the last ten years. This is the most rigorous scientific review of what we know about nutrient requirements for the traditional endpoints as well as for chronic disease prevention.

These dietary reference intakes are actually a collection of dietary reference values. For each nutrient, we've established estimated average requirements for different subpopulations defined on the basis of age, sex and for special physiological stages of life, during pregnancy and during lactation. We've also established recommended dietary allowances for those nutrients for which the scientific base was sufficient to establish an estimated average requirement. And if that scientific base was not sufficient, we recommended an adequate intake. Also, for many nutrients, we found that there was a sufficient knowledge base to establish a tolerable upper intake level.

This shows you the concept of these different terms, and what I'd like to do is just kind of talk you through this slide. (Referring to PowerPoint Slide) Along the X axis, it says, "Observed level of intake." That represents a level of intake that goes from nothing on the left-hand side to some very high level for a nutrient. And in any given population, if the level of intake for a nutrient is very low, close to zero, over a sufficiently long period of time, determined by what the nature of that nutrient is, virtually all of the population will be experiencing an inadequate intake that will lead over time to the appearance of deficiency symptoms.

Again, in the population as the observed level of intake increases, one is able to establish an estimated average requirement within that population, which is the first line that showed under the abbreviation "EAR." If you can establish for a population an average intake, an average requirement, one then can set a recommendation for the entire population at two standard deviations above that average requirement. So the recommended dietary allowances for those nutrients cover the needs of almost everyone in that population.

As you proceed upward on the level of intake, so proceeding more from left to right, you'll reach a level of intake at which the population does not yet show evidence of over-intake, leading to toxicity or other adverse effects. But once one passes that point, you will begin to see an increase within the population of adverse effects. And as the level of intake

becomes very high over time, virtually everyone in that population will be at risk or actually showing evidence of adverse effects.

So this also shows you that for each nutrient there's a range of intakes between the recommended dietary allowance and the upper level that's consonant with good health in that population. Also, what constitutes that range of intake that's consonant with good health varies very much, depending on the nature of the nutrient. That range can be very narrow if it's a nutrient like zinc or fluoride, or it can be very wide if it's a water-soluble nutrient, something like vitamin C.

In the United States and Canada, we've worked together over this last decade, to develop these dietary reference intakes, and governments in both countries are now incorporating these into our policies. Many other countries prepared similar recommendations for their populations, taking into account questions like the nature of the foods that are in their food supply and the bioavailability of specific nutrients within those different food patterns.

The FAO and WHO, through their joint expert consultation, also do scientific reviews and develop the handbook on human nutrient requirements that also plays a very important role worldwide and is used by many countries in their own policy formulations.

Now, why are these type of nutrient recommendations important, particularly when we're considering a question such as this session this afternoon is, about "Hidden Hunger: The Role of Nutrition, Fortification, and Biofortification"? Well, these nutrient recommendations are extremely important, because first of all, they're used in dietary assessment. Around the world, we compare what levels of intake are to these types of recommendations to determine where the shortfalls are within the population.

We also use them for the purposes of planning and procuring food supplies. These can be at the level, for example, of a school, planning meals for its students, or at the level of a population in terms of emergency relief purposes. They're used in various ways in making determinations about food fortification and supplementation policies, planning education programs, planning and evaluating food assistance programs, as the basis for food labeling policies, and also for agricultural policies.

The question as well is what types of food products to develop using the genetic technologies and biofortification, I think is also another extremely important use to which these recommendations can and should be made.

Now, I wanted to point out that, although we have finished this very intensive review of what is known about human nutrient requirements, we now recognize after this decade of work that there still are enormous needs for additional information to answer questions that arose with respect to the specific functions of these nutrients in the course of this review, as well as there were many, many gaps that we identified where we don't have information that permits us to set recommendations.

First of all, we now use in many instances data from adults that we extrapolate to children and then use that information to set the average requirement or the upper level with respect to

children. We don't know how good those extrapolation procedures are, and it would be far better to set the recommendations for children based on studies in children.

We also have insufficient dose response data. We actually need multiple levels of dose intake studies to determine the estimated average requirement for a nutrient and also the upper level. A good indication of the areas for which we lack that information are the nutrients for which we had to set average adequate intake recommendations.

There's a very big gap in data on chronic levels of exposure at the upper levels of intake to be able to establish those ULs. We also have some examples of nutrients for which the adult recommended intakes are greater than the upper level for children, which then poses problems when you're using these data and these recommendations to formulate diets for mixed-stage populations. There are very big communications and education efforts that we have to make yet to the dietitians and others in the health community who are using these reference numbers in patient counseling as well as for other uses.

So ten years after beginning the review that has led to the establishment of these dietary reference intakes, the Food and Nutrition Board is once again returning to the question of – How shall we now proceed? We believe very strongly that we should be consulting broadly in the scientific community, in the biomedical community, and with those who use these recommendations. So we believe in having a participatory process.

We have identified some key questions. We want to know, first of all, over this last ten years how the scientific community has viewed the participatory process that we've used, as well as the scientific processes.

We'd like help in identifying from your perspectives what the issues are that need further discussion, and very particularly we'd like your help and advice on focusing on – What are the criteria that should be used to trigger a new revision to these dietary reference intakes? Among the things that we've considered are:

- Should we think about each nutrient and do a review on a case-by-case basis?
- Should we group nutrients as we did for this last decade's worth of study, grouping the anti-oxidant nutrients together, grouping vitamin D, calcium and phosphorous because of their roles in bone development?
- So should they be reviewed as groups that make sense physiologically?
- Or should we do a comprehensive, as was done in the past, of reviewing all of the nutrients and only making changes in those for which there were a sufficient body of new evidence to make a change?
- If we go on a case-by-case basis, should we only make revisions using criteria that are set very high with a certain number of clinical trials for which there would be a sufficient body of evidence in order to make a change?
- Should we go to a completely different process, perhaps entertaining petitions that would come from the scientific community or from the community that uses these recommendations?

- Or should we revert to the process that the board used for fifty years of every five years reviewing all of the nutrients and making changes in those recommendations, or should there be other criteria that are used?

We have begun initial discussions with the scientific community of these questions. During the experimental biology meetings in the spring, we held a symposium to gather their views from the scientific community. In December of this year, December 8th in Washington, DC, at the National Academy of Sciences, we'll be holding a symposium focusing on – What are the criteria that we should be using to consider revisions in the DRIs? We'll continue consultations through the winter and the spring, and next summer during our annual meeting of the Food and Nutrition Board, we will be deciding, based on this broad consultation, what process to be using.

I'd like to thank the symposium planners for the opportunity to talk with you about this science base that's so important to our food and nutrition policies worldwide, and also to say that we welcome your comments. Thank you.