

Speech (excerpt)

Before Harvard School of Public Health

Remarks by

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Now, we might say that our public policies on nutrition don't have anything to do with these trends, or that we're already doing our best given the state of nutrition science. But I'm not sure that we should settle for that. For example, research by Dr. Willett and his colleagues suggests that, based on the Nurses Health Study and other high-quality longitudinal epidemiologic studies, after controlling for lifestyle covariates, following the recommendations from the government's Food Pyramid was not associated with significantly better overall health outcomes. **And there is now considerable evidence that eating a diet low in fat, as many nutrition experts in and out of government have recommended, may also not improve health outcomes and particularly heart disease risk, if fats are replaced with equivalent or possibly greater calories from carbohydrates.** Moreover, there is also some evidence that consumers are not becoming better informed about dietary and other choices they can make to reduce their disease risks. For example, since 1995, according to FDA surveys, there has been a decline in the level of consumer awareness of some dietary risk factors - not to mention the limits of consumer understanding about the different health consequences of different types of fat.

I know that a number of these fundamental nutritional issues are not fully settled; indeed that's part of the problem. My point is simply that we aren't doing a great job in getting the latest, science-based information to consumers, and we're not doing a great job of encouraging innovations in food and medical technology that can help make it easier for consumers to eat a nutritious, balanced diet given their other lifestyle choices. That shortcoming would justify increased policy attention under any circumstances. But it is an alarming situation when considered in conjunction with the health trends of the past decade.

If we don't start making progress now to reverse these trends, our next generation may grow up less healthy to such an extent that it could threaten the steady and impressive population health gains that we have seen over the past century - gains that were in no small part due to healthier diets and better nutrition. Our public health policies on nutrition have not prevented us from moving in the wrong direction, and the past decade or so has been particularly concerning. And so, throughout our agency and throughout the Department of Health and Human Services, under Secretary Thompson's leadership we are focusing on new ways to address the worsening problem of obesity and preventable disease.

At FDA, where we always try to focus our efforts where we can have the most "bang for the public health buck", our strategic action plan places great emphasis on promoting better diets at the same time we're encouraging the development of more nutritious foods.

As FDA has long emphasized, diet-related health problems are primarily a matter of unhealthy diets, not inherently healthy or unhealthy foods. FDA has also emphasized that our policies need to be solidly based on the latest science, and must emphasize protecting and helping consumers.

That's not changing. **But we are pursuing new initiatives to improve consumer understanding, and to improve the choices of healthy and nutritious diets available to consumers, to reverse the trends of the past decade.**

Some promising innovations are also occurring in food production, and we need to facilitate these developments as well. We have already started to see many foods that are fortified or improved to make them more nutritious, and much more may be ahead. In addition, while the first generation of genetically modified food products were designed to increase crop yields, the next generation of genetic modification might be aimed at making these foods healthier in a person's diet. Foods might even be designed with the specific genetic profiles of different categories of people in mind. So people particularly susceptible to cholesterol might choose to buy avocados grown to be low in saturated fats.

It's quite possible that, within the next decade or two, genomics will not only provide many valuable insights into the development of highly effective, individualized medical treatments; it may also give us the knowledge we need to understand which foods may be particularly risky or beneficial for particular persons, so that we can make specific, individualized adjustments in our diets to prevent some serious diseases. There is a small but growing field called "nutrigenomics" that is seeking to combine the increasing insights from genomics to our understanding of how dietary choices affect our health. Nutrigenomics envisions a future in which personalized genetic profiling takes the guesswork out of deciding what you should eat. By adjusting nutrient composition in a person's diet according to genetic profiles, gene-based nutrition planning could one day play a significant role in preventing chronic disease.

So there are opportunities ahead for health gains through innovation to improve how people can use foods to make their diets healthier. But in order to provide proper incentives for the development of these "next-generation" foods, as well as for making short-term improvements in foods already on the market and healthy dietary choices based on them, it's not enough simply for us to determine that the foods are safe. There has to be a clear regulatory path that enables food producers to make truthful, science-based claims about the health benefits offered by their products. If food producers cannot let consumers know about the benefits for health to the same extent that they can promote the product's taste, its ease of preparation, or its price, we won't see the innovation that we most desperately need - innovation in the nutritional benefits of foods and innovations in helping consumers follow a healthy, balanced diet. This is a hard problem: consumers can reach conclusions about taste, ease of preparation, and price themselves. But for a product's health benefits, they depend on us not only to help prevent them from getting misleading information, but to facilitate their getting up-to-date accurate information about nutrition and health.

At FDA, we firmly believe that there is more that we can and must do to help consumers get good, up-to-date, science-based information so that they can make choices that are based on a better understanding of the health consequences of their diets. We need to continue to improve the nutrition label. This includes providing information on the trans-fat content in foods. And it also includes providing better guidance about the recommended consumption of trans fats, saturated fats, and cholesterol. This is not easy to do. Foods themselves are not inherently unsafe, or we wouldn't allow them on the market. **But the latest nutrition science provides some reasonably clear evidence on which foods should generally be consumed in abundance, which should be consumed more sparingly, and what an overall desirable diet might look like.** Consumers don't so much need information about individual foods as they need information about how individual food choices can fit into a

cancer or possibly folate for colorectal cancer, there may be enough science there that it's worth consumers being aware of it. And it's certainly the case that we need to encourage more development of foods and diets that focus on these and other ways of reducing obesity, heart disease, and other health risks.

These issues are not settled; they are a moving target. I know that updating our guidance to the public can be frustrating and potentially confusing to consumers. We're going through such issues right now as we engage in the process of updating the Food Pyramid. We go through such issues all the time as we develop new evidence on medical treatments, including relatively old treatments like aspirin and postmenopausal hormone therapy. But from a public health standpoint, I don't think we can remain locked in while nutrition science continues to improve, or wait patiently for the day when we get absolutely definitive evidence from large-scale, long-term, randomized clinical trials. We know a lot now, we are learning a lot more, and all of these changes in knowledge ultimately lead to better public understanding, better choices, and better health. In fact, we'd like applied nutrition science to progress much more quickly, and for many of the scientific and policy reasons I've discussed, I'm expecting more rapid progress.

Many of the health claims about such dietary choices as abundant consumption of fruits and vegetables, and substitution in favor of unsaturated fats, and relatively frequent consumption of foods high in omega-3 fatty acids are in the category of considerable good evidence but not definitive evidence. In these cases, and probably in more cases in the future as the science expands, the evidence seems pretty good -- good enough that I think many Americans would appreciate being more aware of it with proper qualifications, even though future more definitive studies might revise our conclusions somewhat about the health benefits of these steps.

Of course, the lack of absolutely definitive research on the health consequences of these dietary choices will have to be truthfully imparted to consumers. There is some encouraging recent applied research on consumer understanding of such qualified evidence. For example, a recent study by the Federal Trade Commission on peoples' interpretation of food nutrition and health claims in advertising suggests that most people are able to accurately interpret health claims that have simple qualifications describing how the scientific evidence is not completely definitive. We need more consumer research on these issues, and we need it quickly, but many of the available consumer studies are encouraging.

Getting this kind of information to consumers is important if we're going to have a positive role to play in helping people make smarter choices about their diets. Because claims that are qualified aren't allowed, right now many of the food products I've described that are likely to be healthier have no easy way on their label to compete with products that advertise their ease of preparation or their good taste. This simple fact has slowed the widespread adoption of eating habits based on much of the valuable research of the past decade. And since these foods are safe, even if only half or less of the health benefits apparent in the research to date actually pans out in the long run, we will have saved many lives over the years by making this information more available in the meantime.

Just because FDA is working to make better information available where the science base is strong but not certain doesn't mean that the FDA intends to relax its enforcement of the accuracy of health claims on foods and dietary supplements one bit. We are more committed than ever to making sure that food and supplement labels are based on sound science, and aren't written in a way that is false or misleading to consumers. Since consumer choices have the greatest impact on public health, FDA must do all it can to ensure that health-related information available to

consumers is truthful and not misleading. Consumers are getting more involved than ever in taking steps to promote their own health, which is a very good thing. And so I view it as a clear public health threat if they then waste their money and time on ineffective treatments as a result of misleading information that doesn't reflect the scientific evidence.

There are many difficult questions related to public policy on nutrition and health. If the questions were easy, we presumably wouldn't have such an enormous disease burden associated with poor dietary choices. But I am optimistic about our ability to meet these challenges. About 35 years ago, a winner of the Nobel Prize in Medicine said that our best work in health was behind us, because all that was left was the chronic diseases and everyone knows that there's little to do about those diseases. And for thousands of years, many pessimists have said that you just can't change human behavior. I'm glad that, in many cases, the evidence refutes them. Fortunately, there is overwhelming evidence that science and technology as well as individual choices can improve, especially when our public policies support desirable changes. We've made tremendous medical progress against heart disease, diabetes, and many other chronic illnesses in the last 35 years. And far fewer people are smoking today, more are exercising on their own, and far more are eating more diverse and potentially healthy diets, than they did 35 years ago as well. We've learned over and over again that behavior will change, that people will choose to live better lives when they have accurate and compelling information about their choices. And when coupled with appropriate public health policies and consumer protections, we've seen that food and medical products respond to the demands of consumers and the new insights of science. And so in closing I want to ask for your best ideas and your help with the many urgent and difficult food issues that FDA is facing today. We have some great opportunities to make our foods safer and more secure, and to find more effective ways to combat obesity and other preventable illnesses. The public health challenges are great, but the opportunities to make a real difference for the health of the public have also never been greater. Thank you very much.