2020 DIETARY GUIDELINES ADVISORY COMMITTEE

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PUBLIC MEETING

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THURSDAY
MARCH 28, 2019
DAY 1 OF 2

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The Advisory Group met in the Jefferson Auditorium, at the headquarters of the U.S. Department of Agriculture, 1400 Independence Avenue, Washington, DC, at 9:00 a.m., Barbara Schneeman, Chair, presiding. The meeting allowed for public viewing, both in-person and by Web.

PRESENT

BARBARA SCHNEEMAN, PhD, Chair
RONALD KLEINMAN, MD, Vice Chair
JAMY ARD, MD
REGAN BAILEY, PhD, MPH, RD
LYDIA BAZZANO, MD, PhD
CAROL BOUSHEY, PhD, MPH, RDN
TERESA DAVIS, PhD
KATHRYN DEWEY, PhD
STEVEN HEYMSFIELD, MD
HEATHER LEIDY, PhD
RICHARD MATTES, PhD, MPH, RD
ELIZABETH MAYER-DAVIS, PhD, RD
RACHEL NOVOTNY, PhD, RDN, LD
JOAN SABATÉ, MD, DrPH
LINDA SNETSELAAR, PhD, RD
JAMIE STANG, PhD, MPH, RDN
LINDA VAN HORN, PhD, RDN, LD

ALSO PRESENT

BRANDON LIPPS, JD, Acting Deputy Under Secretary, USDA

DON WRIGHT, MD, MPH, Deputy Assistant Secretary for Health, HHS

SCOTT HUTCHINS, PhD, Deputy Under Secretary, USDA

JACKIE HAVEN, MS, RD, USDA

COLETTE RIHANE, MS, RD, USDA

EVE STOODY, PhD, USDA, Designated Federal Officer

RICHARD OLSON, MD, HHS

JANET de JESUS, MS, RD, HHS

JULIE OBBAGY, PhD, RD, USDA

TUSAREBECCA PANNUCCI, PhD, MPH, RD, USDA

DAVID KLURFELD, PhD, USDA, Co-Executive Secretary

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P-R-O-C-E-E-D-I-N-G-S

9:00 a.m.

DR. STOODY: Good morning.

My name is Eve Stoody, and I'm the Designated Federal Officer for the 2020 Dietary Guidelines Advisory Committee, and I'm also the Lead Nutritionist for nutrition guidance at USDA's Center for Nutrition Policy and Promotion.

It is really my pleasure to welcome everyone, both here in the audience and those of you online, to the first meeting of the 2020 Dietary Guidelines Advisory Committee. We are really so excited to get this work underway, and we thank you for your interest and your work in this process.

I do want to start with just a couple of housekeeping items. For those of you here in person, you'll notice that we have badges. You need to have either a USDA official badge or that sticker to go through the halls of this building. So, please keep that sticker on. It designates to security that you are a part of this group.

Also, you will notice that some people have blue dots, and those blue dots indicate that they are staff. It also says "staff". So, if you have any questions at all, please reach out to a member of the staff, and they can help you or they can direct you to someone who can assist you.

Now, finally, if you need some refreshments or lunch later, the cafeteria is down wing 3.

Now we are all here with a common goal to improve the health of our nation. We know that what we eat and drink matters. And yet, we know that we are very far behind in meeting the Dietary Guidelines. On average, Americans have a score of a 59 out of 100 on the Healthy Eating Index. If you look at the lefthand side, that graph there, it shows that Healthy Eating Index scores have increased slightly over the last 10 years. Now, the righthand side, you can see that Healthy Eating Index scores are slightly higher among our youngest and our oldest Americans, but,

overall, there is a lot of room for improvement. And yet, research shows us that moving towards a healthy diet, a diet that aligns with the Dietary Guidelines, can have health as well as economic benefits in terms of healthcare costs.

The Dietary Guidelines are mandated to reflect the preponderance of scientific evidence and to be published jointly by the Departments of Agriculture and Health and Human Services at least every five years. And it is important to reexamine the evidence to provide current, credible, science-based advice to all Americans now from birth into older adulthood.

We want to set the stage by saying that USDA and HHS are committed to ensuring that our process to develop the 2020-2025 Dietary Guidelines for Americans is transparent, inclusive, and science-driven. And those are three terms that really drive our work on a daily basis. And you will hear more about how we're working to address these goals throughout the presentations today and tomorrow.

So, for our agenda today, this morning we'll have some opening remarks and formal swearing-in of the Committee. That would be followed by a quick break. And then, I'll do an overview of the Committee's Charter, operations, and timeline, and that will be followed by remarks by our Chair and Vice Chair, and then, lunch.

And then, this afternoon I'll begin with a presentation around responding, the Department's response, USDA's and HHS's responses to the National Academies of Sciences' Engineering and Medicine Study on the process to establish the Dietary Guidelines for Americans. We will, then, get into a discussion about the approaches that the Committee will use to examine the evidence. So, that includes the Nutrition Evidence Systematic Review, formerly known as the Nutrition Evidence Library, or NEL, as well as data analysis and food pattern modeling.

We'll also have a discussion about a new step that we're implementing, which is the

peer review of the systematic reviews conducted by the 2020 Advisory Committee. Then, I'll close the day with a little bit of a discussion about opportunities for public engagement throughout this process before we close for today.

Now, for the public record -- oh, maybe I should note, too, that the agenda is available at dietaryguidelines.gov. And we will post the recording of this meeting, as well as all of the slides and any of the materials that are used today, at dietaryguidelines.gov. Please allow one to two weeks for posting, just so we have all those pieces.

We will also have meeting minutes from this meeting and eventually a transcript, but that will take a little bit longer for us to get and get posted.

For the public record, 17 of our 20 members are here with us today, who Mr. Lipps will introduce shortly. Doctors Donovan, Naimi, and Taveras were not able to be here today, but they will tune in as they are able.

Should they have any questions or comments during the Committee's discussion, they will send them to one of our colleagues, Stephanie Fu, who will come to this podium and speak on their behalf.

Please note that this is a meeting of the Committee that is open to the public to observe. If you have any comments to the Committee, we encourage you to submit those through the written public comment process, so they become an official part of the public record.

We will also have two opportunities for the public to provide oral comments to the Committee. We had one last round, and we're going to have two this round. And we'll talk more about that later today and at dietaryguidelines.gov.

So, we're so happy to have our leadership from USDA and HHS here with us today to kick off this exciting phase of our process. I'm pleased to introduce Brandon Lipps, Acting

Deputy Under Secretary of the USDA Food, Nutrition, and Consumer Services mission area, and Administrator of the Food Nutrition Service, or FNS. As you may be aware, FNS is the lead agency from USDA for the 2020-2025 Dietary Guidelines process.

Acting Deputy Under Secretary Lipps joined USDA in 2017 from Texas Tech University System, where he was the Chief of Staff and Director of Federal Affairs in the Office of the Chancellor. Before that, he served as counsel and senior professional staff to the U.S. House Committee on Agriculture, where he led the nutrition policy team in developing key initiatives in nutrition assistance.

We really appreciate Mr. Lipps' leadership here at FNS, and please join me in welcoming him.

(Applause.)

DEP. UNDER SEC. LIPPS: Good morning. Good morning.

That's better.

Thank you, everybody, for being here today.

Thanks, Dr. Stoody, for that kind introduction.

On behalf of Secretary Perdue, who couldn't be with us here today -- he is on travel -- I want to welcome everybody, our Committee and our audience, to the first meeting of the 2020 Dietary Guidelines Advisory Committee.

Many thanks to Dr. Don Wright from the Department of Health and Human Services for their great partnership in this process, and for Dr. Hutchins, from our REE mission area here at USDA, for joining us today. They're going to give you comments in just a few minutes on their perspectives as well.

I'm very excited to announce we have more than a thousand people joining us today in this room and, also, by webcast. The participation by the public is a very important part in this process. You will hear us talk over and over about ways that we have increased

transparency in this process. I think the process has done a wonderful job in the past. Many folks didn't know how to access many of the transparent opportunities that were in various places on our website. We have worked on revamping much of that stuff and provided more opportunities for input, beginning with listening sessions prior to putting the questions out for public comment, and continuing as we go throughout this process.

Committee Members, we are excited that you're all here today. I'm very excited that 17 of you were able to travel here relatively quickly for the first meeting of the Committee today. We've asked for a significant commitment from each of you. You've accepted our invitation, and we thank you. You all have very important roles in your day jobs, and we thank you for the time that you have committed here.

In the next phase we're kicking off today, the Departments collectively are asking you, as scientific experts in nutrition and

public health, to conduct an independent, rigorous review of the scientific evidence. Your role is to examine that science. Our roles at USDA and HHS are to develop the Dietary Guidelines, and we take our roles just as seriously as we believe that you do.

Every federal nutrition program and all federal nutrition activities nationwide rely on the Dietary Guidelines. It impacts millions of lives. And for the first time, the 2020-to-2025 edition will do so from birth to adulthood, the entire lifespan.

At USDA, this means programs and initiatives like our Women, Infants, and Children, often known as [the] WIC Program, will be more heavily influenced by the Dietary Guidelines. Our Child and Adult Care Food Program, which provides important nutrition to children in daycare, both public and in-home throughout the country; our SNAP Education Initiatives, which provide important nutrition advice to those on our SNAP program, and, of

course, MyPlate, the nutrition resource for all consumers, as the public looks to us for nutrition advice on how to eat a healthy diet.

It goes without saying -- Eve said it; I told you we would say it again -- but it's imperative that our process be transparent and that it be evidence-based. We must ensure that what we put into the Guidelines is grounded in the latest science, not the latest study to hit the headlines, the latest science across studies over time and of high quality.

Thank you, Committee, again for taking on this very important role. It is a difficult role and one that will take much time commitment from you, and we appreciate you providing that.

We are committed to making the process and the work of this Committee to be transparent and inclusive every step of the way. Since the process started to develop the 2020-to-2025 Dietary Guidelines early last year, we have worked hard to make sure of that, fostering public trust and input. We've built transparency

into every stage of the process. We've improved how we make it available, and moves as simply as redesigning our website.

We want the public to comment. The public comment period for this phase of the process opened on March 12th and will remain open for the entire time the Committee is doing its work. All of you listening today, we ask you to comment on this process every step along the way. There will also be opportunities for oral comments to the Committee at two of our hearings.

After the Committee submits its reports to us and disbands, and the public comment period closes, we will open a new public comment period on the scientific report provided from the Committee.

All told, from the start of this process, where we saw public input on the topics and questions the Committee will examine, because they are important to the Dietary Guidelines we will develop, to our call for nominations for Advisory Committee members, to the public comment

periods that I've just talked about, we have made sure that the public will have had about two years to participate in this process.

Transparent, inclusive, and science-driven, that's our commitment, both to you, the Committee, and to the public, as this process moves forward.

At this time, I have the great pleasure of introducing the Committee. As I say each of your names, I would appreciate you standing up.

And for those of you in the audience, I would appreciate you holding your applause until we finish introducing all members.

I want to first welcome the Chair of our Committee, Dr. Barbara Schneeman. Dr. Schneeman, thank you for your willingness to lead this incredible effort.

Along with her, our Vice Chair, Dr. Ron Kleinman. Dr. Kleinman, thank you as well for this very important role.

You all please stay standing. You can

have the joy of standing as all your partners go.

(Laughter.)

Also serving on the Committee:

Dr. Heather Leidy;

Dr. Joan Sabate;

Dr. Carol Boushey;

Dr. Regan Bailey;

Dr. Jamy Ard;

Dr. Elizabeth Mayer-Davis;

Dr. Steven Heymsfield;

Dr. Kathryn Dewey;

Dr. Lydia Bazzano;

Dr. Richard Mattes;

Dr. Rachel Novotny;

Dr. Linda Van Horn;

Dr. Teresa Davis;

Dr. Linda Snetselaar;

And Dr. Jamie Stang.

Joining us remotely are Dr. Elsie Taveras, Dr. Sharon Donovan, and Dr. Tim Naimi.

Committee Members, thank you all very much for volunteering your valuable time to this

very important process. We look forward to your independent review of the process and your recommendations to the departments.

Please give a healthy round of applause to our Committee members.

(Applause.)

You can be seated.

I felt a little bit like I was back in my old job calling names coming across the stage.

(Laughter.)

Thank you for welcoming our Committee.

It's now my pleasure to ask the Chair and Vice Chair to come forward and stand with me as we administer the oath of office to the Committee.

Dr. Schneeman and Dr. Kleinman, and other Committee Members, please raise your right hand.

Both of you please come over here, yes.

(Committee members sworn-in.)

Thank you, everyone.

(Applause.)

In closing this portion, again, Committee, I want to thank you for your willingness to serve. We are going to thank you often. We have very high expectations of you, and we know we are asking a lot of time commitment to you. So, thank you again for that. Thank you for your expertise in your fields and your commitment to ensuring dedication to public health.

It is now time for you to hear from my colleague at the Department of Health and Human Services, Dr. Don Wright. It is my pleasure to introduce Dr. Wright.

He is the Deputy Assistant Secretary for Health and Director of the Office of Disease Prevention and Health Promotion, as we all know, ODPHP, which drives the Dietary Guidelines work for HHS with us here at USDA. As Director of ODPHP, in addition to the Dietary Guidelines, Dr. Wright provides leadership for Healthy People 2020 and oversees the recently-released Physical

Activity Guidelines, also important, we should all note.

Please give a warm welcome to our friend, Dr. Don Wright.

(Applause.)

DEP. ASST. SEC. WRIGHT: Well, thank you all. And thank you, Mr. Lipps, for opening today's session of the Dietary Guidelines Advisory Committee.

As most of you know, the U.S. Department of Health and Human Services works hand-in-hand with the U.S. Department of Agriculture in the creation and development of the Dietary Guidelines for Americans. USDA and HHS have worked collaboratively on the Dietary Guidelines for Americans since 1980, when the first edition was actually released.

My office, the Office of Disease Prevention and Health Promotion, is the HHS lead for the Dietary Guidelines and works closely with the Center for Nutrition Policy and Promotion at USDA.

Mr. Lipps, I am very proud to say that my office and your office work so collaboratively, have in the past, and will continue to work together collaboratively, in support of the Advisory Committee work.

Since 1990, the National Nutrition Monitoring and Related Research Act has mandated that the Dietary Guidelines be republished by USDA and Health and Human Services at least every five years. This particular legislation is important because it ensures that the Dietary Guidelines remain a priority for both Departments.

The law stipulates that each edition of the Dietary Guidelines should be based on the preponderance of the science evidence and medical knowledge current at the time, and should be used as the basis for federal food programs. This drives us to work continually to improve the rigor of the process and underlies the Guidelines, and to ensure that all programs related to food, nutrition, and health are based

on the strongest scientific evidence.

As you probably know, health promotion and disease prevention is a top priority for the U.S. Department of Health and Human Services. To that end, nutrition guidance based on rigorous scientific research and evidence is critical to the health and well-being of our nation.

At HHS, our agencies use the Dietary Guidelines in a variety of ways. Certainly, the Dietary Guidelines are used for current guidance delivered through our grant programs and through our educational materials. They're also used in our food assistance programs, like the Older Americans Act nutrition programs. They're used in our National Health Objectives, such as the Nutrition and Weight Status Objectives in the Healthy People Initiative. They're used in nutrition monitoring and research, and certainly, they're used in the regulatory process as related to food labeling and fortification.

Over the years, the Dietary Guidelines development process has continued to evolve and

to reflect advances in nutrition science, and to increase the transparency of the entire process. Last year, in 2018, USDA and HHS introduced a new step in the process. We asked the public, as well as our federal agencies, for comments on proposed topics and scientific questions to guide the work of the Committee. We received over 12,000 comments on these topics and questions, and considered the comments based on criteria such as the importance of it as related to public health or the potential impact on our federal food programs.

To the Committee, HHS and USDA hope that the final topics and questions will help streamline the work of the Committee by focusing on the evidence related to nutrition and a wide variety of health outcomes across the lifespan. For example, the Committee will be reviewing evidence on the relationship between dietary patterns consumed at each stage of life and the risk of development of cardiovascular disease, of type 2 diabetes, and of certain types of cancer.

Without question, this is a very important work.

The public can also view all the topics and questions, including public comment on those initially proposed, on www.dietaryguidelines.gov. Everyone will hear more about the topics and questions at tomorrow's session.

We may all work in different areas of health, but we all share a common mission: to enhance the health and well-being of all Americans. Unfortunately, too many Americans engage in behavior such as unhealthy food choices and physical inactivity that lead to poor health. As a result, 60 percent of adults in the United States have a chronic disease, and 40 percent of adults have two or more chronic diseases.

But in that news there is good news. We know many chronic diseases, including obesity, can be prevented through both a healthy diet and through physical activity. HHS recently published the second edition of the Physical Activity Guidelines for Americans. We released

those in November of 2018. My office, the Office of Disease Prevention and Health Promotion, led this initiative, using a similar advisory committee with subject matter experts in the area of exercise. Move Your Way is a promotional campaign to encourage the public to meet the recommendations listed in the Physical Activity Guidelines for Americans.

Preventing chronic disease like obesity, type 2 diabetes, and cancer are very important public health priorities within HHS and to our agencies, especially to the National Institutes of Health, the Food and Drug Administration, and the Centers for Disease Control and Prevention in Atlanta.

Nutrition is a key focus in the Healthy People Initiative, which my office leads on behalf of Secretary Azar. For almost 40 years, Healthy People has been providing science-based National Objectives with ambitious, yet achievable goals for improving the health of the nation.

In this way, Healthy People can serve in many ways as a roadmap for the nation's health prevention and disease prevention activities. Healthy People is very much about understanding where we are now, planning for where we want to be in the future, and then, providing guidance on how we can make those improvements over the next decade.

The Dietary Guidelines help to inform the foundation of the nutrition and weight status goals and objectives within the Healthy People 2020 and the soon-to-be-released Healthy People 2030 Initiative. For example, the Healthy People 2020 objectives promote increasing the consumption of fruits, vegetables, and whole grains in the diet. Other objectives provide goals and targets to reduce the consumption of saturated fats and added sugars over the decade. Healthy People 2020 also aims to reduce the proportion of children and adults who are obese.

Let me say another office within HHS, the Office of Women's Health, is looking forward

to the Advisory Committee's science-based recommendation to promote women's health across the lifespan. We know that proper nutrition during the early stages of life is critical to support healthy growth and development during childhood and to promote health and prevent chronic disease throughout adulthood.

Because of this, the Committee will examine questions focused on infants and toddlers from birth to age 2 and women during pregnancy and lactation. Certainly, your work will help ensure that a strong scientific foundation underlies the Dietary Guidelines we provide for all Americans across the lifespan.

Well, in closing, I want to take just a minute to thank you for your willingness to serve on this Committee. It is truly a labor of love, and I do think the impact of your work is very large and has the opportunity to improve the health of the nation. So, thank you for your willingness to serve.

I did want to say that the Assistant

Secretary for Health, Admiral Giroir, was, unfortunately, unable to be here today, but he sends his well wishes as well as his thank you.

I'm very pleased and confident that this group has the right expertise. We have the right people at the table to carry out the Committee's charge, and I know your work will be instrumental in helping the people of the United States of America live healthier and longer lives. I look forward to working with all of you over the next year and a half as you review the scientific basis.

Thank you very much.

(Applause.)

DEP. UNDER SEC. LIPPS: Thank you again, Dr. Wright.

I will say that we do have a great partnership, and I do believe that the two Departments working together helps to make this a better and more robust process as we move forward. So, we appreciate you and your staff and that partnership.

I now have the pleasure of introducing a colleague from here at USDA, Dr. Scott Hutchins. As we discussed earlier, we are taking all the opportunities we can to increase the transparency and the science-based portions of this process. The Agricultural Research Service, under the direction of Dr. Hutchins, is going to help us do that as we move forward.

Dr. Hutchins is the Deputy Under Secretary for USDA's Research, Education, and Economics mission area, which, as I mentioned, includes the Agricultural Research Service, and it is now part of our Dietary Guidelines team.

Dr. Hutchins was sworn-in by USDA Secretary Perdue in January of this year and joined USDA after 32 years at Corteva AgriScience. He is also an adjunct professor of entomology at the University of Nebraska-Lincoln.

With that, we would like you to come provide us a few remarks, Dr. Hutchins.

(Applause.)

DEP. UNDER SEC. HUTCHINS: Thank you,

Mr. Lipps, for that introduction.

And good morning, and thank you all for joining us here today for this inaugural event.

And, I also want to make a special thanks to the Committee for their service and for all the work that will be occurring over the next 14 months. It will be, indeed, critical to us, but also, I know, a tremendous amount of work on their part. And we look forward to the output.

I was sworn-in, as indicated, on January 29th by Secretary Perdue as the Deputy Under Secretary for this mission area. And since that time, I've been really busy learning and gaining perspectives from a number of stakeholders on a number of topics, including this topic, which I'm very pleased to help sponsor on behalf of the USDA with Mr. Lipps. And since I've joined, I have been pleased to have the opportunity to work with so many dedicated colleagues within the USDA.

My background is in entomology. I'm

an entomologist and have a past in the private sector, as you indicated. And I have always known about the talent of USDA scientists and their dedication to their mission throughout my career, but to be here and to see it firsthand has been truly inspiring. And I could not be more proud to be part of their team.

REE, as we call it, Research, Education, and Economics, is a research-based organization, as the name implies. And I strongly believe that research matters. Science-based and data-driven is the mantra for REE and, also, for Secretary Perdue, and it should characterize, also, the focus of this Committee and process, as indicated in the mission.

Indeed, the systematic review of scientific evidence is a critical and invaluable part of any deliberative process. Humans have evolved as a species over millennia, not in five-year increments. And evolution doesn't work that way. Individuals don't evolve; populations evolve. But what does change continuously is our

knowledge and understanding of science through research and how to interpret those new learnings and decipher the complex interactions to better inform policies. So, the work of this Committee is critical in that regard.

But what is unique to humans as a species is our ability to choose and the freedom to choose. And that freedom provides us the opening to provide guidance with those choices. And I recognize that there are a lot of opinions out there and a lot of different perspectives to draw upon. I have it, actually, in my own family. I have three grown children, all well-educated and all responsible adults. One is a vegetarian, one is a frequent meat consumer, and one is an omnivore. And all three are content in their choices, and what's most important to me is that they're all respectful of each other and their choices.

From these three families, I have seven grandchildren age 6 and under. In their raising from my children, they are ensuring at

every meal that they have a well-balanced opportunity and are focused on nutrition for their children.

Just a few words about the mission area I want to share with you because I think it will be useful to this Committee. We have four agencies within the Research, Education, and Economics mission area. The National Institute for Food and Agriculture, or NIFA, sponsors research at universities across the country, especially in 1862 and 1890 land grant institutions, cutting-edge research.

The Economic Research Service is also part of this mission area, and it collects and analyzes data on food availability, and has created just a tremendous amount of information and reports that can be supportive of this Committee and implementation.

The National Agricultural Statistics Service generates crop forecasts and plays an important role in helping with pricing and other types of information.

And the intramural research organization for USDA, the Agricultural Research Service, or ARS, generates the foundational information for surveillance of dietary intake and nutritional status.

These four agencies, along with the Office of the Chief Scientist, combines and provides the guidance to the Department on a number of topics, including these from a science and research standpoint.

The USDA has maintained food composition data, for example, since 1891. This task was recently totally revised with the creation of the FoodData Central, a one-stop shop website for all data products related to food composition and delivery of dietary surveys.

In partnership with the Centers for Disease Control, the Agricultural Research Service analyzes food intake reports and calculates nutrient intakes for all age groups, identifying shortfall or excess nutrients which can be correlated against a variety of health

endpoints. This dietary component is called What We Eat in America, and is the only nationally-representative snapshot of the changing dietary habits and nutrient intake for Americans. And I believe it will be useful to this Committee.

Mission area scientists stand ready to assist the Committee in mining these databases as needed, and with newly-expanded scope to include children from birth to 24 months and pregnant women, we can support the new amount of information as well, in support of this Committee.

At USDA, we are for sound science and the preponderance of quality evidence as the basis for your recommendations. I welcome the Committee to not only analyze what we have, but to provide support to us in identifying important gaps in knowledge that you find in the course of your work, so that that will help guide the research community in efforts for the future to fill such gaps.

Research is a priority of USDA;

Secretary Perdue, who has stated clearly the departmental goals that he wants to provide all Americans access to a safe, nutritious, and secure food supply. He says it this way: "We are here to do right and feed everyone."

And in that sense, we again thank you for your service. We welcome the guests and look forward to the stakeholder input. And we thank you for your contribution and your involvement.

(Applause.)

DEP. UNDER SEC. LIPPS: Thanks, Dr. Hutchins.

I think the only thing standing between us and a break is a photo opportunity.

(Laughter.)

So, I'm not sure -- we have a very cozy stage, which actually I like. I like to have our teams at the smallest table we can get in, so we can sit around and debate. And I hope you will have plenty opportunity to do that.

But, with that, I want Dr. Hutchins and Dr. Wright to join me and the Committee up at

the center of the stage. And I think our colleagues will tell us where to stand.

Thank you all very much.

DR. STOODY: And those here in the audience, you're welcome to stay or you're welcome to break. And we'll reconvene at 10:15.

(Whereupon, the above-entitled matter went off the record at 9:35 a.m. and resumed at 10:14 a.m.)

DEP. UNDER SEC. LIPPS: Welcome back, everybody.

Eve is very forceful, and when she said, "Take your seats," you did that very fast. So, we're waiting for 10:15 for the few stragglers who were all out, based on our former commitment timeline.

I just wanted to take a minute. I am not always real good about reading from my script, but I did this morning. And staff are not good about bragging on themselves when they write your comments. But they really keep the wheels turning on this front and have done a lot

of work to get us to this place.

So, I would like to ask all of the USDA and HHS staff to stand up, and let's take a moment and recognize them for their hard work.

(Applause.)

Thank you all very much. It's been a lot of work to get to this point, and we have a long way to go.

With that, I will leave the stage and let you all get on with your program.

Thank you.

DR. STOODY: Thank you, Mr. Lipps.

Okay. So, we are going to get right in and start talking about the Committee's Charter, operations, and then, timeline.

And again, my name is Eve Stoody, and I'm the Designated Federal Officer for this 2020 Dietary Guidelines Advisory Committee.

So, we are going to start with the foundation. And Dr. Wright did speak to this as well. The Dietary Guidelines are mandated under the National Nutrition Monitoring and Related

Research Act, which was passed in 1990. And the bullets here are verbatim from that Act.

That Act requires the Dietary Guidelines to contain nutritional and dietary information and guidelines for the general public;

That they will be published jointly by the Secretaries of Agriculture and Health and Human Services at least every five years;

And that they will be promoted by each federal agency in carrying out any federal food, nutrition, or health program;

And finally, that they will be based on the preponderance of the scientific and medical knowledge which is current at the time it is prepared.

And those things really do inform our process, thinking about the preponderance of evidence, speaking to the general public, making them applicable to Americans. And you'll see those things, really informed the kind of criteria that's used in our systematic review

process, as well as the data that's used to inform the process as well.

Now some of you may also know about the Agricultural Act of 2014. It mandates the inclusion of infants and toddlers and women who are pregnant, beginning with the 2020-2025 Dietary Guidelines for Americans.

Now, historically, the Dietary Guidelines have really focused on Americans ages 2 years and older. Some of the earlier editions did speak to pregnancy -- really all the editions have spoken to pregnancy to a certain extent. Infants and toddlers were addressed in some of the earlier editions, but, then, later, it's been two years and older.

However, that evidence base has continued to grow. And really, for the past, I would say about 10 years, the Departments have kind of had this -- there's been this kind of discussion around should we expand to include these age groups. And then, the Agricultural Act passed in 2014 which really mandated that to

occur.

So, the upcoming edition will cover the entire lifespan from birth through older adulthood. And we're really excited about that change. It's resulted in, you know, we have new experts. This Committee is the largest committee we've ever had, and that's to reflect that expertise. That has also allowed us to, within our federal staff -- and we'll talk more about that -- we have a number of federal staff who have expertise in that area that have come into this process as well. And I think it will make it an even stronger process.

This Dietary Guidelines Advisory Committee is what's called a discretionary committee. We're not required to do it. The Departments have asked to have this Committee. It is established to accomplish a specific task. And as it has been noted before, this Committee has been established to provide independent, science-based advice and recommendations to be considered by USDA and HHS in the development of

the next edition of the Dietary Guidelines.

This Committee is formed and governed under what is known as the Federal Advisory Committee Act. We note that just because there are formal processes. There are formal processes for establishing the Committee, how you operate, how we oversee your work, and your termination, which sounds very dramatic.

(Laughter.)

But the ending of the Committee's work.

So, there are rules and processes. And so, we'll work to help ensure that this process stays within the Federal Advisory Committee Act.

Members of this Committee are appointed as special government employees. There's another type of member which is called a representative member. And special government employees are selected really based on your recognized expertise and expert knowledge relevant to this Committee. And so, you are

asked to review the evidence as independent scientists, and not representing a specific viewpoint.

As a part of the Federal Advisory Committee Act, a charter must be filed with Congress before a Federal Advisory Committee can meet or take any action. The charter for the 2020 Dietary Guidelines Advisory Committee was filed with Congress on October 5th of 2018, and it describes the Advisory Committee's purpose, duties, and general operations. That charter is available at dietaryguidelines.gov. We have previously shared this charter with the Committee as well. And if you go to dietaryguidelines.gov, you click on the Resources tab, and you can see a link directly to the charter.

Okay. So, as noted, one of the things that the charter describes is the Committee's objective and scope. And you will see us talk about this at every meeting. This is really the governing -- what the Departments are asking the Committee to do. And so, we will come back to

this regularly. You'll see it presented at every meeting.

The 2020 Dietary Guidelines Advisory Committee will:

Examine the evidence on specific topics and scientific questions identified by the Departments. We'll talk a little bit about those in the next slide, and then, again, in a presentation tomorrow.

Then, after reviewing the evidence, develop a report that outlines its science-based review and recommendations to the Departments with your scientific justification for those recommendations.

At the end of this scientific review, you will submit your review -- you will develop that report and submit that report to the Secretaries of the Department of Agriculture and Health and Human Services for consideration as the Departments develop the next edition of the Dietary Guidelines.

Now, to those specific topics and

supporting scientific questions, Dr. Wright spoke to this a little bit in his opening remarks. But, for this round, for the first time, we identified the topics and questions before establishing the Committee. And we'll talk a bit why we took that route here later this afternoon.

These topics and questions were identified by the Departments, but with federal input as well as public comments. They reflect a continued focus on patterns of what we eat and drink as a whole, on average, and over time, now from birth into older adulthood.

And just briefly, the topic areas look at dietary patterns, beverages, added sugars, dietary fats, seafood, frequency of eating, and, of course, questions focusing on the birth to 24 months and pregnancy and lactation.

And those topics and questions are also available now at dietaryguidelines.gov. We posted those in September of last year. So, they are available for viewing there at this time.

Okay. The Committee's task is time-

limited. The Committee will terminate after delivery of its final report to the Secretaries of USDA and HHS or two years from the date the charter was filed with Congress. And that's a requirement of FACA. And so, again, the date that the charter was filed with Congress was October 5th of last year, either the report submitting or that date, whichever comes first.

We do want to note that, while the charter was filed in October, the Departments request the Committee's report by May of 2020. And that is to allow the Departments to meet the mandate to release the next edition of the Dietary Guidelines within five years of the last edition, which means that we need to release the Dietary Guidelines by December of 2020. So, we're asking you to complete this work by May, so that we have that time to meet that mandate.

The Committee is expected to hold five meetings, and we are excited, for the very first time, to be identifying those meeting dates at the beginning of the process. This is the first

time we have ever done this. Usually, we plan them as we go. With such a large Committee of fantastic experts, it was really necessary to try to get these on your calendars as soon as possible. And also, we hope that it allows the public to follow along in the process as well and to plan for these meetings.

So, the meeting dates are here. I will also show them a couple of other times today. Four of the meetings will be held in Washington, D.C. We do plan for the fourth meeting to be out of the D.C. area in Houston, Texas, so to go out of the usual D.C. hotspot. And then, two of the meetings, we'll have the opportunity for oral comments to the Committee. So, that will be the meeting in July and the meeting in January we'll have the opportunity for the public to register to provide oral comments to the Committee.

Now I will say registration is not open yet.

(Laughter.)

So, I would love for you all to be really excited about this, but we'll announce registration as that becomes available and as we get to the individual meetings. And we'll announce that through dietaryguidelines.gov and through our listserv. And I'll talk more about how to sign up for that here in a bit. So, we hope that having these dates really does help you follow the process and plan for engagement.

The Committee's charter does allow for the formation of subcommittees. Those subcommittees should be composed of members of the parent Committee. So, these 20 members dividing into groups of subcommittees. And that's to help it accomplish its objectives and to help facilitate this review of the evidence.

So, the purpose of the subcommittees is to review the evidence and, then, provide advice to the parent Committee. So, the subcommittees aren't speaking to the Departments directly. You're working as subcommittees, reporting that information to the parent

Committee, the full Committee. Ultimately, your recommendation, your report, is on behalf of the whole Committee to the Departments.

Each subcommittee will conduct its work together between the meetings of the full Committee and will provide updates for deliberation and decisions during the public meetings. So, we really encourage you -- I mean, this conversation needs to happen in a public forum, having discussion and deliberations across the Committee. And so, that will be the expectation. And I think this meeting there's a lot of presentations of us talking about the process. In future meetings, we'll include a lot more discussion of your review of the evidence, where you are, things that need to be discussed at the full Committee. So, at the end of the day, when you submit your report, everybody has been engaged and understands the recommendations that are being made by the Committee.

I do want to note, as Mr. Lipps had staff stand up, we do have a number of staff who

will be helping to support the Committee. But the ultimate conclusions and recommendations are of the Committee. So, we are here to help facilitate the work, to ensure that we follow processes, but, at the end of the day, it's your report and the Committee's recommendations to us.

Now I do want to note that public comments are accepted throughout the Committee's deliberations and on their report. We'll talk more about this at the end of the day when we talk about opportunities for public engagement. But I do want to note that this is in addition to just being more deliberative. It is a requirement of the Federal Advisory Committee Act.

And so, we will have public comments, I think as Dr. Wright noted, opened on March 12th, and it will continue throughout the Committee's deliberations. So, at any time you can go in and provide written public comments to the Committee. You can find that link; we do it through regulations.gov, but you can go to

dietaryguidelines.gov and access that information. I think, so far, we've gotten like 49 public comments. So, if the public has comments, we encourage you to submit them through that route.

I do want to note that the Committee did complete an administrative training prior to this meeting. That meeting included an introduction to the Federal Advisory Committee Act from a USDA Committee Management Officer. It included ethics training by USDA Office of Ethics staff. It included guidance on interactions with media from the USDA Food and Nutrition Service's Office of Communications.

And I'll say, just generally, Committee members are asked not to speak on behalf of the Committee. So, if stakeholders reach out to them with information, they will request that that information be submitted through the public comment process. And that's to allow it to be a part of the official record and to be a part of the official process. When

there are media requests, those are directed to the Departments, and to only discuss information that is publicly available. Really, those are elements that are requirements around FACA, but also as their appointments as special government employees.

I will note that slides from that administrative training will be posted at dietaryguidelines.gov when we post the information for this public meeting.

Okay. Creating the Dietary Guidelines. As has already been talked about by our leadership, it is a partnership between USDA and HHS. I do want to note that, and some of you may know that, the responsibility for serving as the administrative lead rotates every five years. So, we're at USDA today because USDA is serving as the administrative lead for the 2020 edition, just as HHS served as the administrative lead for the 2015 process. However, as has been noted by our leadership, this is very much a partnership, and we will continue to work together in creating

the final edition of the 2020 Dietary Guidelines as well.

Now, within the Departments, the USDA Center for Nutrition Policy and Promotion within the Food and Nutrition Service and the HHS Office of Disease Prevention and Health Promotion play lead roles in the Dietary Guidelines process. Just to note that these two offices are led by Jackie Haven for the Center for Nutrition Policy and Promotion and Dr. Wright from ODPHP.

Within those offices, we have a number of staff that this is what we do year-round, all the time. Whether we have a committee in place or not, we're preparing for the next committee. We are looking at process improvements. We are developing websites. So, it is something that we do. It is literally a part of our job description, supporting of the Dietary Guidelines at all times. And it's communications and all the different elements that come with this work.

We are also very pleased to have some federal liaisons supporting this process who have

really come on to support the Committee, so to support the work of the Committee. Some of those are with USDA and, also, from agencies within HHS, including FDA, CDC, and NIH.

And then, there are additional staff, other staff. And one of our things is trying to really identify roles and responsibilities and distributing workload and responsibilities. We will have staff who are specifically focused on supporting the review of evidence, and those will be identified in presentations later today.

And then, finally, to note we do have a science writer who will help support in the development of your report, and we have worked with her on a few different rounds, and she has been wonderful to work with. So, we will have that support as well.

So, just in closing, again, the Committee has a very important role, which I think you've heard several of us speak to so far. And that is to describe the state of current nutrition science. Each edition of the Dietary

Guidelines that the Departments develop build upon the previous edition with scientific justifications provided and informed by your work.

And your report, your final report, will ultimately also be posted for public comment on your report. And again, there's public and agency comment. But, at the end of the day, this is really a foundational piece for providing scientific justification for changes.

As you heard, too, we really thank you for this work. I think there's been comments that everybody keeps saying it's a lot of work.

(Laughter.)

So, it is a lot of work, and we really do appreciate your time, your expertise, and we look forward to receiving your report.

So, with that, I am happy to answer any questions, if you have any at this time, related to the charter, the timeline, or your operations.

(No response.)

All right. And you always know where to find me if you have questions.

Okay. So, I am now so pleased to introduce the Chair of the 2020 Dietary Guidelines Advisory Committee, Dr. Barbara Schneeman.

Dr. Schneeman's distinguished career in nutrition science and chronic disease prevention reflects diverse experience tackling the complex issue from multiple perspectives. It includes 28 years at the University of California, Davis, serving in leadership roles nationally, including with the U.S. Food and Drug Administration, and lending her expertise to influential committees internationally, such as the Food and Agricultural Organization and the World Health Organization.

At UC-Davis, Dr. Schneeman educated food science students on nutrition principles and food policies, trained graduate students in food nutrition science, and conducted research on dietary factors associated with reducing risk of

chronic disease.

For nine years, she served as the Director of the Office of Nutrition Labeling and Dietary Supplements at the U.S. Food and Drug Administration.

Dr. Schneeman, also, importantly, brings seasoned insights into the Dietary Guidelines process specifically. She served as a member of the 1990 and '95 Dietary Guidelines Advisory Committees and, more recently, she served as a member of the National Academies' study on the process to establish the Dietary Guidelines, which completed its work in 2017.

So, please join me in welcoming Dr. Schneeman.

(Applause.)

CHAIR SCHNEEMAN: Thank you, Eve.

I'm going to take the prerogative to sit with the Committee. It seems appropriate.

And so, first of all, let me extend my thank you to the Committee members for your agreement to serve on this Committee. It is a

major commitment of time and talent. I will echo or reinforce what you have been hearing.

But I have to say, seeing the outstanding roster of experts who have agreed to serve, made the decision to serve as Chair much easier. I feel I have a good group to work with.

I also want to recognize the expertise and experience of the staff who will be working with us. You all are an incredible valuable resource for the task ahead of us.

And Dr. Stoody and the officials that we have heard earlier from HHS and USDA have certainly presented the significance of the Dietary Guidelines themselves for the federal government programs. And from my experience, I know how important they are in shaping programs. They've also clearly outlined the elements that are key to the task of this Committee.

So, in considering the task ahead of us, I just wanted to emphasize a few principles that are important to me in moving the work forward and keeping us on task. Certainly, the

importance of understanding the Committee's charter. What we will hear about the topics and questions, this is what we've been asked to provide independent scientific evaluation, and we need to focus on that work.

Also, the evaluation of the available science is central to our task. And whenever possible, we will make conclusions and recommendations based on that evaluation.

This central task will rely both on the expertise of the Committee members as well as the support of the staff to make sure we are reviewing the relevant data and studies to answer the questions that are in the topics and questions.

And then, as a third point, I do want to make sure that we abide by the legal framework of the Federal Advisory Committee Act. Having worked for the federal government, I know how important it is for the credibility of our work to adhere to those requirements. And certainly, we've learned more in our training. We've heard

more about it today.

And I think a reminder that you will hear often is, while we will be using subcommittees for our working groups because we have to progress the work between meetings, the decisionmaking process and the deliberation that the Committee as a whole will go through will be a part of the public process. And that's to make sure we're consistent with the FACA requirements.

So, related to these principles and some of what we've been hearing, this first meeting of the Committee has been structured to both inform the Committee about the topics and scientific questions, the evidence that is available and that we can tap into, and how it will be examined and evaluated, and to obtain input from the Committee on several items to establish our framework for the Committee's work, and that the subcommittees can, then, rely on for their work to bring things forward to the parent Committee.

I can't emphasize enough how fortunate

we are to have the support of expert staff from USDA and HHS, many of whom you will be hearing from today and tomorrow, and have the opportunity to gain more insight and, also, ask your questions; and again, to be part of that public deliberation to ask those questions.

So, I'm also very pleased that Dr. Kleinman has agreed to serve as the Vice Chair for the Committee. Given that this is the first DGAC that has been asked to review and make recommendations for pregnancy, lactation, and B through 24, his expertise will be valuable in guiding the Committee's deliberations and decision-making in this area.

Dr. Kleinman brings vast experience as an esteemed pediatrician who has served in many leadership roles. Nutrition support of infant and children and nutrition and public health policy are among his major research interests. He is currently Chair of the Massachusetts General Hospital's Department of Pediatrics, Physician-in-Chief of the Mass General Hospital

for Children, and a Charles Wilder Professor of Pediatrics at Harvard Medical School. He served as the Chair of the AAP Committee on Nutrition and is the Editor of the Academy's Pediatric Nutrition Handbook.

Dr. Kleinman has served on numerous scientific advisory committees and boards, from several committees for the National Academy of Sciences' Maternal and Child Health and Obesity Prevention for Young Children, as well as Adolescent Health and Development, to serving on the Scientific Advisory Committee for the Sesame Street Workshop since 2009.

I think of special important for our work, Dr. Kleinman served as Chair of the Workshop Planning Committee for the Dietary Guidelines Birth to 24 Months Project from 2012 to 2013 and brings that expertise to us.

So, I'll let you make some opening remarks.

VICE CHAIR KLEINMAN: Thank you very much, Barbara.

I'm going to keep my remarks very brief and just perhaps add a little bit to what you've already said.

First, I really do appreciate this opportunity to work with all of you on this project. We'll call it a "project". I think it's a wonderful opportunity to learn for me and, also, for us collectively to be able to evaluate the evidence base that's evolved since the last Dietary Guidelines, the current Dietary Guidelines came out; and, in particular, to see or provide advice on how this evidence base can inform the implementation of these into guidelines.

On a personal and professional note, I am a pediatrician and have spent most of my professional career in research in the field of nutrition. But, to echo what some of the previous speakers have said, I am a father, and I know it's hard to believe, I'm a grandfather as well.

(Laughter.)

So, both from a professional and personal position, I am very excited that these Guidelines will now incorporate the entire lifespan from pregnancy right through the early periods of life.

This isn't a new concept. I was looking for a quote, and I came upon one by Frederick Douglass. So, that goes back over 150 years. And to paraphrase him, he said, "It's easier to build strong children than to mend broken adults."

And so, from that, we have finally come to the point where we recognize the importance of what I think most people now call the first thousand days and how environmental factors, and, in particular, nutrition, influences the development of all of the systems that not only have immediate impact on the life of the child, but impact the development of health and disease later in life.

So, I'm approaching this with really so much enthusiasm to see how we look at the

evidence base and come up with some recommendations for that period of life.

That's about all I have to say. A mentor of mine once said that, "At some point in a conversation, everything that needs to be said has been said. It's just that everybody hasn't said it yet."

(Laughter.)

And so, hopefully, we'll be able to conduct our business that way.

(Applause.)

DR. STOODY: So, thank you, Dr. Schneeman and Dr. Kleinman.

We are going to adjust our schedule a little bit. I'm going to go ahead and give the presentation about responding to the National Academies' report, since we are running a little bit ahead. So, I'm going to put that up on the slide presentation. So, just we'll pause one second, and then, we'll reconvene here in just literally two minutes.

(Whereupon, the above-entitled matter

went off the record at 10:44 a.m. and resumed at 10:45 a.m.)

DR. STOODY: Okay. I hope everybody had a great lunch.

(Laughter.)

So, yes, just a little shuffle in the agenda. One of the things we wanted to do was to do a presentation around the National Academies' report on the process to update the Dietary Guidelines. So, we'll spend some time walking through that here today.

In 2016, Congress directed a comprehensive study on the process to update the Dietary Guidelines. USDA then commissioned the National Academies' Health and Medicine Division to undertake this study. The Health and Medicine Division did convene a 14-member committee that conducted this independent study for 18 months. Three members of our Dietary Guidelines Advisory Committee also served as members of that HMD committee, Dr. Schneeman, Dr. Ard, and Dr. Boushey.

That study concluded in two reports, the first on Optimizing the Process for Establishing the Dietary Guidelines. And it was really focused on the Advisory Committee, so the selection process for establishing this Committee. And then, the second report was really on the remaining aspects or the larger aspects of the process. And so, it was a broader scope and covered everything kind of beyond the selection process. Those two reports were released in February and September of 2017.

So, just to start off, USDA and HHS thank the National Academies and the committee for their work and recommendations. And again, USDA was commissioned to do the report, and that's why we asked HMD to do it. But the report was to both Departments, and both Departments have worked together in responding to the recommendations.

So, we want to speak a bit about how we respond to these recommendations for the 2020 process. Some of the things that we considered

when reviewing the recommendations was conforming with relevant laws and regulations. So, we've already talked a bit about the Federal Advisory Committee Act, and that was something that we had to think about and look at the recommendations in relation to that Act.

Also, federal ethics laws and regulations. There were some things that really had input from our ethics, how conflicts of interest are defined and how we work within the discussion around conflicts of interest.

We also considered time and resources. We're mandated to develop the Dietary Guidelines every five years. So, how do we fit these pieces within the process, and particularly, for this process. So, what we'll talk about today relates specifically to this Advisory Committee and the 2020 Dietary Guidelines.

We also talked about potential implications on other federal advisory committees. There are currently 400 active committees within USDA and HHS. And so, things

that we do in this Advisory Committee can impact other advisory committee processes. So, we kind of looked at it with a larger global perspective as well.

And then, we also had input from stakeholder listening sessions. So, after the reports were released, USDA and HHS hosted a listening session where a number of stakeholders came in and provided input around those recommendations. And the transcripts from those listening sessions are available on CNPP's website.

The reports did provide overarching values and, then, specific process recommendations. So, there were five values that they recommended to improve the integrity of the process, to develop credible and trustworthy guidelines. And those five values are: to enhance transparency; to promote diversity of expertise and experience; to support a deliberative process; to manage biases and conflicts of interest, and to adopt state-of-the-

art processes and methods.

Overall, USDA and HHS support these values and will continue to integrate steps to address these goals. Even when we were going through the individuals recommendations, we would come back to these values and kind of think about, are there elements that we can address related to these values?

I will say these have been values that we have worked towards prior to the report, but it was nice to see those kind of affirmed in the committee's report, kind of informing our process as we move forward.

Now I will say that the first report included four recommendations, and the second report included seven recommendations. And I'm literally going to walk through each of the recommendations, talk about what the recommendation was, and our response to that recommendation. So, it will be a little recommendation after recommendation, but we really felt like it deserved the time to kind of

walk through each one and talk about our response to those recommendations.

So, the first recommendation related to -- and again, the first report was around establishing the committee -- so, the first recommendation was that the Secretaries of Agriculture and Health and Human Services should employ an external third party that would help narrow down the list of nominations to develop a primary and alternate list of nominees for consideration by the Departments in establishing the Committee.

So, again, this was really, historically, in a way, this is typically done as the Departments receive nominations and the Departments select the Committee. And the recommendation here was for the Departments to receive the nominations, but for us to ask a third party to narrow down the list to kind of a primary and secondary kind of slate. Now our response, due to resource limitations really around cost and time, we did not utilize a third

party for the Committee selection process.

I should note there were other elements to the recommendation around establishing criteria for the Advisory Committee, and that is something that we did do. We did develop screening criteria. That criteria was included with our call for nominations. So, we were telling people, these are the criteria that we are looking at when we're looking at the individual nominees.

They related to, they were criteria around the educational background, professional experience, demonstrated scientific expertise, obligations under the Federal Advisory Committee Act, and requirements regarding a balanced membership.

And one of the other things, kind of going back to that value of transparency as well, we now provide more information on our website on the process that we use within the Departments to establish the Committee. So, again, identifying those criteria in advance, and then, just telling

people more. If we have always had processes; we just haven't necessarily described them, and that has been something that we are working to do, is add more transparency through our website.

The second recommendation was that the Secretaries of USDA and HHS should make a list of provisional appointees open for public comment, including short biographies and any known conflicts, for a reasonable period of time prior to appointment.

We did explore incorporating this recommendation. However, in the interest of provisional appointees, the Departments chose not to implement this recommendation out of privacy concerns. And specifically, there wasn't a way that we could guarantee -- I mean, those comments could have been made public, and we didn't want to subject potential Committee members to kind of being within -- having all those comments in a public space.

The third recommendation was that the Secretaries of Agriculture and Health and Human

Services should disclose how provisional nominees' biases and conflicts of interest are identified and managed. And there were four elements to this.

The first was by creating and publicly posting a policy and form to explicitly disclose financial and non-financial biases and conflicts.

The second was to develop a management plan for addressing biases and conflicts for the panel as a whole and individuals as needed.

The third, certifying that a federal ethics officer independently reviewed and judged the Advisory Committee's biases and conflicts of interest.

And then, finally, documenting how conflicts of interest were managed in the Dietary Guidelines Advisory Committee report.

Related to this recommendation, we just want to note that we agree that managing potential conflicts of interest and minimizing bias is essential to this process. USDA and HHS do work to assess and manage potential conflicts

of interest and work to manage bias through a number of different steps in our processes, and I'll walk through a few of these here.

First, during the Committee's selection process, everybody, all of the individuals who were under final consideration for the Committee were asked to submit a confidential financial disclosure report, a form known as the OGE 450. And that form is publicly available on the web. So, everybody was asked to do that prior to selection.

Historically, the way advisory committees have been formed, that step is done after you have been appointed. So, after members are appointed, they do the conflict of interest. In this case, we did it before. So, before you are selected, before we had done final identification of members, that step was taken. That completed report was reviewed by ethics officials within the USDA Office of Ethics.

And then, we also in this round asked for some specific information in nomination

packages. And so, typically, it's send a 10-15-page CV. And we really asked for specific information: education, employment, peer review publications, presentations, blogs, funding sources, other affiliations. And we really did this for awareness, but also to support establishing a Committee with broad representation and balance across many different considerations. So, it was really helpful in our process to kind of see the broad range of elements in the CVs.

So, that was during Committee selection. During Committee service, the USDA ethics official will conduct annual review of each member's conflict-of-interest form.

Ethics training will also be provided to the Committee annually. We've already done that ethics training prior to this meeting for this year, and we'll do it again before the Committee is terminated.

In general, the approaches to examine evidence are protocol-driven. They're rigorous.

They're objective. And those elements help to minimize bias.

And we'll ask the Committee to also provide a summary of how it worked to manage potential conflicts of interest and minimize bias in its scientific report.

The fourth recommendation was that the Secretaries of Agriculture and Health and Human Services should adopt a system for continuous process improvement, to enhance outcomes and performance of the selection process. And we will continue to do this. We'll look at how this process worked.

We have spent a lot of time talking to other -- we have 400 other advisory committees. What is the process you use, understanding how other agencies work in this space, and also reviewing best practices just across the nutrition community and medical community as well.

Okay. So, as I noted, the second report included seven recommendations. So, we

have seven more to go.

(Laughter.)

The first recommendation was that the Secretaries -- and again, this is on the larger process, beyond kind of the selection process, all the other elements. The Secretaries of Agriculture and Health and Human Services should redesign the Dietary Guidelines process to prioritize topics to be reviewed in each cycle, and then, to redistribute the current functions of the Advisory Committee to three separate groups.

And so, first, the three groups are the Dietary Guidelines Planning and Continuity Group. And that group would work to monitor and curate evidence generation, identify and prioritize topics, and then, provide strategic planning support across the Dietary Guidelines cycles.

The second was to convene what they call technical expert panels to provide content and methodological considerations during

evaluation of the evidence.

And the third was that the Advisory Committee, which they phrase the Dietary Guidelines Scientific Advisory Committee, would then interpret that scientific evidence and draw conclusions.

Now, in response, three separate groups have not been established, again, part due to time and resource constraints in relation to establishing discretionary advisory committees. All those would also have to be discretionary, which, again, establishing one discretionary advisory committee is a process. And so, to develop additional ones -- and they would have to be Federal Advisory Committees -- is a process. Particularly the Continuity Group would be an advisory committee.

However, in response to this recommendation, and to support a more deliberative and transparent process, USDA and HHS, as you heard and as we've discussed, with federal agency and public input, did identify the

topics and questions to be examined by the Committee prior to establishing the Committee. So, doing the topics and questions first was, in part, due to the NASEM report, to kind of pull that out as a separate step.

I do want to note that there are relevant existing Nutrition Evidence Systematic Review, which was formerly known as the NEL. There are existing NESR systematic reviews, including those conducted by the 2015 Committee, as well as some that were completed by recent pregnancy and birth to 24 months technical expert collaboratives that are available for the Committee's consideration. So, they are relevant, and they've addressed these topic areas and relate to the questions of interest.

The second recommendation of the second report was that the Secretaries of Agriculture and Health and Human Services should provide the public with a clear explanation when the Dietary Guidelines omit or accept only parts of conclusions from the scientific report.

And I'll say, as we've noted on our website, we'll continue to expand our response to these recommendations as we move into the respective steps. So, we're just not there yet. So, the Departments will respond to this recommendation as we move to this phase.

The third is that the Secretary of Agriculture should clearly separate the roles of the USDA Nutrition Evidence Library, now the NESR, staff and the Dietary Guidelines Scientific Advisory Committee, such that the NEL staff plan and conduct systematic reviews with input from technical expert panels, perform risk-of-bias assessment of individual studies, and assist the Committee as needed.

The NEL systematic reviews should be externally peer-reviewed prior to being made available for use by the Committee, and that the Committee synthesize and interpret the results of systematic reviews and draw conclusions about the entire body of evidence.

Now, in response, I'll say that the

roles and responsibilities of the NESR staff and the Committee will be clearly outlined. Dr. Obbagy will talk a bit about the NESR process later today, and we'll continue that discussion about what the roles and responsibilities are. There are separation of responsibilities.

Due to time and resource constraints again, NESR will not be conducting -- and this is just the point we made a minute ago -- we won't be conducting systematic reviews with input from separate technical expert panels during the work of the Committee. NESR will be working directly with the Committee. However, as I noted, there are some relevant systematic reviews within kind of the NESR topics and questions they've done in the past that are relevant for the Committee to consider.

We do want to note that we did add a step, which is the peer review of the systematic reviews that you do. And Dr. Klurfeld will speak to that later today. The Agricultural Research Service is going to help facilitate that peer-

review process. And that was to align with this recommendation and just generally align with best practices.

The fourth recommendation is that the Secretary of Agriculture should ensure all Nutrition Evidence Library systematic reviews align with best practices by enabling ongoing training of the NEL staff, enabling engagement with and learning from external groups at the forefront of systematic review methods, inviting external systematic review experts to periodically evaluate the NEL methods, and to invest in technological infrastructure.

The NESR team acknowledges that systematic review science and supporting technologies evolve continuously. NESR's Continuous Quality Advancement Initiative -- so, they have work where they do this already -- involves enhancing staff knowledge and skills through ongoing training and professional development, leveraging the expertise, and collaborating with methodologists from other

leading systematic review organizations, such as Cochrane, as well as the HHS Agency for Healthcare Research and Quality, or AHRQ. And they are working and do have steps that they'll speak to around expanding technological infrastructure.

For the fifth recommendation, it was that the Departments should enhance the method known as food pattern modeling to better reflect the complex interactions involved, variability in intakes, and range of possible healthful diets. And the response is that a food pattern modeling team has worked to transparently document its method and incorporated the latest dietary intake data for analysis.

The topics and questions that have been identified also allow for more explanation of variability in intakes across the lifespan and examination of a range of possible healthful diets based on available evidence. And Dr. TusaRebecca Pannucci will speak to that process later today.

The sixth was that the Secretaries of Agriculture and Health and Human Services should standardize the methods and criteria for establishing nutrients of public health concern. And again, the data analysis team has worked to transparently document those steps first, and, also, to standardize those methods and criteria for establishing nutrients of concern. And that won't be discussed in today's data analysis presentation, but it will be discussed, and there has been work to standardize those methods.

And then, finally, the National Academies' committee recommended that the Departments should commission research and evaluate strategies to develop and implement systems approaches into the Dietary Guidelines. The selected strategies should begin to be used to integrate systems mapping and modeling into the Dietary Guidelines process.

And again, I will say that -- and I think Dr. Wright mentioned, too -- we are continuously looking to add methods and to

address kind of advances in reviewing science. So, for example, USDA established the Nutrition Evidence Systematic Review in 2008 because systematic reviews are really becoming the state-of-the-art approach for informing clinical and public health guidance. And so, it is something that we are staying on top of and trying to advance. And I will say we have done some initial exploration into systems approaches and will continue to explore this option.

So, just in closing, there are fact sheets that are available on our website with these recommendations and our responses -- again, if you go to dietaryguidelines.gov, and you click on Resources.

We've also been asked to submit a report to Congress with responses to these recommendations. And so, we'll be doing that later this year.

With that, I'm happy to answer any questions, if there are questions on this topic.

CHAIR SCHNEEMAN: I will make a

comment, personal comment, as a Committee member. And having been involved with the recommendations from the National Academies, I am impressed with what you have been able to incorporate from the recommendations for this particular cycle. I think it's fair to say that the committee was concerned about the timing, how well things could be integrated.

And I guess one thing that might affect the deliberation of our Committee was the recommendation about, thinking about it generally, around those three committee structures, but, definitely, the principle behind it was thinking about continuity over the cycles, so that topics could be identified moving forward that needed to be addressed, and that some recommendations probably don't need to be addressed with each cycle.

So, I'd be interested in your comments about that concept of continuity and how the Departments have thought of that.

DR. STOODY: I mean, we agree, and it

has been something we have talked about. I think there has been this discussion of do we need to address every topic every time, but that's a hard thing to -- it is not easy to say which topics you're not addressing because in the field of nutrition there's so much interest and there's research published every day on different topics. So, thinking about that mandate for the Dietary Guidelines to be based on the preponderance of current scientific evidence, you know, being sure that we meet that mandate while also not duplicating or going into topic areas we don't need to necessarily reexamine.

So, I think that the idea and part of the conversation on the federal level has been trying to think about now we've added this emphasis around birth to 24. What's the emphasis in 2025? And so, I think we would like to have that more continuity -- the concept of it or the principles behind it, I think we support. It's how to implement the infrastructure to get us to that goal and, also, to represent the

preponderance of current science.

So, it's something we're definitely talking about, and we already are thinking about kind of what can we do and steps that we can take to prepare for the 2025 process, and this is part of that conversation.

All right. Any other questions?

CHAIR SCHNEEMAN: Thinking about this Committee's work, the current DGAC Committee's -- it's not working. I'll try this one. There.

Thinking about this particular DGAC Committee's work, I anticipate that the public comments will grow as the process moves forward. And we have been given a set of topics and questions that the Departments have asked us specifically to address. So, if we see things that go beyond that mandate that the Committee has, is there a way that we can acknowledge the relevance of the topic or question, but not necessarily deal with it directly? I'm just thinking, again, in terms of how do we handle something like that in the framework of these

recommendations.

DR. STOODY: Absolutely. So, the Committee is asked to limit its review of the evidence to the topics and questions that have been identified by the Departments. If there are topics -- I mean, we are looking at -- I mean, we do this every five years. And so, I think that if there are topics and questions that you feel that are relevant in this process, there is an opportunity to acknowledge those. It's really we're asking you to focus your review to evidence on those topics and questions which Janet de Jesus will speak to tomorrow. If there's anything beyond that, I think there can be a place in your report to speak to, we feel like, in 2025, looking at X, Y, and Z. Yes, I think that's totally appropriate.

MEMBER MATTES: As a corollary of that, given the topics, do we have the authority to request specific reviews? I mean, you are going to develop the database that we work on. What if we have ideas that additional data is

necessary to answer the question well?

DR. STOODY: So, I'm not sure if I totally understand the question. You can work within the topics and questions.

MEMBER MATTES: You're going to be preparing systematic reviews --

DR. STOODY: With your input.

MEMBER MATTES: -- for us to work with, right.

DR. STOODY: With your input, yes.

MEMBER MATTES: Okay. So, we can request a review on a particular facet within our topic area --

DR. STOODY: Within the topic.

MEMBER MATTES: -- that you may not have thought of yet?

DR. STOODY: That's part of the conversation, yes --

MEMBER MATTES: Good.

DR. STOODY: -- with the subcommittees, yes, and the Committee. Yes, it's just staying within those topics and questions,

but you'll be involved in kind of -- and part of the discussion tomorrow, for example, will be on discussion of which neurocognitive health outcomes to consider or which cancer outcomes to consider. So, you are a group of experts brought together to inform those systematic reviews.

Any others?

MEMBER HEYMSFIELD: In one of your slides, you mentioned five values to improve the integrity of the process. And one of those was support a deliberative process. What's a deliberative process?

DR. STOODY: You ask the Committee.

(Laughter.)

Well, I think the way that they spoke to it was that it had a lot of input. I mean, that it had input from the Committee. I mean, I think, for us, it's that we're not operating in isolation. The Departments aren't operating in isolation. We have input from the Committee. There is the public comment period. That there is the systematic review piece. I mean, that

there are different elements. It is kind of many sources of evidence feeding into the process; that there are different roles and responsibilities, and that there are multiple pieces to developing the Guidelines. But, I mean, you all are on the Committee.

Dr. Schneeman or Dr. Boushey, if you like to add to that?

But, for us, it's really been trying to make sure that we get input from various sources; that we took that topics and questions process, the development of topics and questions outside of the Committee process. It's kind of the division of responsibilities, having public input on that, kind of having a lot of input in different places.

MEMBER HEYMSFIELD: Okay.

MEMBER ARD: I'll just add to that. I think part of that discussion, too, centered around the idea of diversity of thought within the Committee. So that, from a deliberative standpoint, if everyone on the Committee already

has a predetermined perspective on Topic X, then that's not deliberation; that's just consensus.

And so, the idea was, when you're constituting the Committee, that we're looking not just at the typical conflicts of interest around association with industry or those types of things, but also diversity of thought and perspective in being able to say, if presented with scientific evidence that is contrary to my previous line of research, then I'm able to discuss that, deliberate on that, and then, come to a conclusion that is based on the evidence.

MEMBER NOVOTNY: Sort of jumping off of what Dr. Kleinman said earlier, I'm struck with the fact that we're at this point pursuing the idea of initiating the Dietary Guidelines starting in pregnancy and at birth. And what an amazing opportunity it is to kind of track from the bigger-picture, overarching question of prevention of something as chronic as obesity in this country, and while we're all about trying to meet nutrient needs, we're also trying to do it

in a manner that is prevention-oriented.

And I'm just curious -- and maybe this will come up later during our deliberations specifically -- but it is impressive to me that we have this opportunity to look at this upcoming generation of individuals who will be followed through this new movement in the establishment of these Guidelines. I'm wondering if there is a plan to look at some sort of tracking of this upcoming generation for that purpose, to determine whether these benefits can, in fact, influence health and longevity in years to come.

DR. STOODY: It is a fantastic research question.

(Laughter.)

So, maybe you can engage on that, yes. I think that's a larger conversation, looking at the impact of the Guidelines for this next generation after these Guidelines come out. So, I think it's separate from this specific process, but a very important part of the process, yes.

CHAIR SCHNEEMAN: And perhaps thinking

about what can be in the Committee's report, I believe we can make research recommendations, that that has been a standard part of the process.

DR. STOODY: Absolutely, yes. It's an important part, we think. It does help inform research that's done. So, yes, it's a very key part.

Okay. So, if there are no other questions, we will break for lunch. And please reconvene here at 12:45 to continue the discussion.

So, thank you.

(Applause.)

(Whereupon, the above-entitled matter went off the record at 11:16 a.m. and resumed at 12:47 p.m.)

DR. STOODY: Good afternoon. I hope everyone had a great lunch, and we'll get going here in just one second.

Before we start, I want to have my colleague here, Jessica Larson, who is going to

give a little bit of update for those people who are viewing the webinar, this meeting today, by YouTube.

MS. LARSON: Hello. For those who have received the announcement, there is a second link for this afternoon. We hope everyone has switched over. If you are on the original link from this morning, we ask that you switch over. You can find that link either by going to #dietaryguidelines. We will also be emailing the link out, and it has been on this screen for those who were watching during the break. But, if anyone has a pen and paper, you can also write it down. So, I'll read it out loud.

It is https://youtu.be/big/m7_gyjw8.

Once again, we will be tweeting that out #dietaryguidelines. And you will also be receiving an email.

The new link has already started, but the old link will expire soon. So, we appreciate you switching over for the afternoon session.

Tomorrow there will be two links. So,

please check your email. For those who are viewing online, there will be a morning link and an afternoon link.

Thank you.

DR. STOODY: Thanks, Jessica.

So, for those who are just joining us for this afternoon's session, this morning we wrapped up our original agenda items a little bit early. And so, we covered the response to the National Academies' report presentation prior to the break. However, I do want to note, as we noted at the beginning of the meeting, all of the presentations will be archived on our website. So, there will be an opportunity to see that, if you're interested in viewing it. Additionally, we will have the slides from that presentation available on our website as well.

So, today, this afternoon, we are going to move on in the agenda and talk about the approaches for examining the evidence. Our next speaker is Colette Rihane, Director of the Office of Nutrition Guidance and Analysis in the Center

for Nutrition Policy and Promotion, or CNPP, within the Food and Nutrition Service at USDA.

A Registered Dietician and 22-year veteran, she has years of clinical experience in nutrition counseling and evaluating nutrition status for patients across the lifespan. She has been with USDA for nearly 20 years. At CNPP, she provides oversight and guidance for the process of developing the Dietary Guidelines for Americans and for CNPP's Nutrition Evidence Systematic Review, the review of nutrition data, and the development of USDA's Food Patterns, and the updates to the Healthy Eating Index.

Please join me in welcoming Colette Rihane.

(Applause.)

MS. RIHANE: Thank you very much, Eve.

Welcome back, everyone. I hope everyone had a great lunch. I'm happy to see everyone here.

We have a lot of good information for you this afternoon. Please, we're going to have

to try to make sure you don't fall asleep after lunch.

(Laughter.)

So, what I'm going to do right now is just going to introduce to you various approaches for examining the evidence, those approaches that will be used by the Committee members in examining the scientific evidence.

Reviewing the science, answering questions on a variety of topics, and developing a scientific report of findings is like completing one gigantic puzzle. It's important to remember that not all questions are created equally, and not all questions can be answered using the same approach.

There are several approaches that can be used to answering a particular question. Listed here are the three approaches that will be discussed in more detail over the next few hours. We have several speakers who will be discussing each one individually.

One approach that is used is, as you

have heard the term, Nutrition Evidence Systematic Reviews. These are systematic reviews that inform the Committee's work and will be supported by the Nutrition Evidence Systematic Review team, or the NESR team, at USDA's Center for Nutrition Policy and Promotion.

These reviews will either be new, original systematic reviews that the NESR team and the Committee will conduct to answer the questions on diet and health by searching for, evaluating, synthesizing, and culminating all relevant peer-reviewed studies.

Or they will also be able to look at existing systematic reviews, which I believe has been alluded to, that the NESR previously conducted which are relevant to the current topics right now and the questions being investigated.

Another approach is food pattern modeling. These are analyses that are performed using national datasets as well as findings from systematic reviews to help us understand how the

changes in dietary recommendations might impact meeting nutrient needs across the U.S. population.

Additionally, data analyses will be looked at, which are a collection of analyses used with national datasets to help us understand the current health and dietary intakes for Americans. The data help make Dietary Guidelines be more practical, more relevant, and also achievable.

As you can see, each of these approaches has a unique place in assisting the Advisory Committee and answering the questions that need to be answered.

As I mentioned already, not all questions are created equally, and therefore, not all questions are systematic review questions. That's very important to remember.

The best approach to answering a question depends on the nature of the question and the type of information needed to answer that question. As the next speakers describe each of

these approaches in more detail, you will see that each approach is clearly protocol-driven, completed in a very rigorous and objective manner, and, most importantly, designed to help minimize bias.

This is just one of the many commitments our agencies have made in support of the National Academies' study that Dr. Stoody talked about earlier before the break. Together, these approaches for examining the evidence are meant to be complementary approaches that, together, provide a robust evidence base for all the questions across the topics that have been identified.

The approaches provide unique contributions to help answer questions, and it should never be suggested that one approach is superior to another. In all these cases, federal staff across USDA and HHS, which you've heard already we have a vast team to assist, will be supporting the Committee in various ways during its review of the evidence, regardless of the

approach being used.

So, we're going to start to first look at the first of three approaches that we are hoping to introduce to you. And that review be will by Dr. Julie Obbagy.

Dr. Obbagy has been with the Center for Nutrition Policy and Promotion for nearly 10 years reviewing evidence to support work to develop and implement dietary guidance, to help improve the health and well-being of Americans. She is leading the work of CNPP's Nutrition Evidence Systematic Review team to support the 2020 Dietary Guidelines Advisory Committee's review of the science.

She will spend her time today providing an overview of NESR and answer questions the Committee may have afterward.

Please welcome Dr. Julie Obbagy.

(Applause.)

DR. OBBAGY: Great. Thanks, Colette.

So, my job here today is to give you all an introduction to Nutrition Evidence

Systematic Review, or what we refer to as NESR. So, I'll talk a little bit about who we are and what we do. I'll walk you through our systematic review methodology, and talk a little bit about our methods for using and/or updating existing NESR systematic reviews. And then, finally, talk a little bit about how we plan to make our work transparent and accessible.

So, the first item that I'd like to address today is that we have recently changed our name. We're now known as Nutrition Evidence Systematic Review, or NESR. Previously, we were known as the Nutrition Evidence Library, or NEL. NEL was launched about 10 years ago. And pretty much since our inception, there's been a pretty common misperception that we're more of a traditional library in the sense that we're sort of a brick-and-mortar library or an online database that houses every nutrition research article ever published, which is not at all what we are.

And so, we are really hoping that by

changing our name to Nutrition Evidence Systematic Review, we'll do a better job of communicating to people that we really are a team of scientists who specialize in conducting systematic reviews. But, to correspond with the name change, I think it's important to note that this does not reflect a change in our role, and it doesn't reflect a change in our systematic review methodology.

So, this slide show our NESR team members. I am pretty proud to be representing such a well-qualified and dedicated group of individuals. All of our analysts do have advanced degrees in nutrition, public health, epidemiology, or a very closely related field. We're also supported by three librarians, all of whom have advanced degrees in library science.

Our staff has received extensive hands-on training over the years as well as professional development ongoing, and really are able to perform all of the steps in our process independently.

Our staff also has a lot of experience. Many have been with the team for the last three to four years. Some of us have been with the team much longer, 10 or 11 years. So, we're all very much looking forward to supporting your work and reviewing the evidence over the next year and a half or so.

So, the core mission of NESR is to conduct systematic reviews on food and nutrition-related topics that can be used to inform U.S. federal nutrition-related guidance and programs. And so, just to make sure we're all on the same page as to what a systematic review is, I've just put the definition for sort of how we define and describe what a systematic review is on this slide. In essence, it's a research project that answers a very clearly-formulated scientific question by searching for, evaluating, analyzing, and synthesizing nutrition evidence.

And so, Dr. Stoody did a nice job of going through all of the USDA and HHS responses to the recent National Academy study that came

out on the process to develop the Dietary Guidelines. So, I won't go into much detail here, other than to say that the responses to the NESR-related recommendations are found on our website, as well as on dietaryguidelines.gov; and that I do hope, as I walk through the rest of the presentation, you'll really be able to see how we do really support the five values that are listed on the top of this slide. And I think you'll get a good, clear understanding of what the role of the NESR staff is versus what your role as the Advisory Committee will be.

In addition, since our inception, I think we've really worked hard to ensure that our process does remain up-to-date. And so, we really did appreciate the emphasis in the report on continuing to do that. And, of course, as we prepared to support your work as the 2020 Committee, we did do a very thorough evaluation of our methods and our tools, just to make sure that we are, in fact, aligned with current best practices, both in the field of systematic review

methodology as well as in the field of nutrition science.

So, as I walk through our process today, I will highlight a few areas where we have made some advancements, either by engaging with or leveraging some of the advancements made by others in the field, like Cochrane, which is a global leader in conducting systematic reviews, as well as Health and Human Services, Agency for Healthcare Research and Quality, AHRQ.

And then, again, we've also continued with professional development. We've also really worked to leverage technology where we can, all with the goal of ensuring that at the end of the day our work is as high quality and credible as it possibly can be.

So, before I dive more specifically into our methodology, I did want to set the stage for how our staff will work to support you as a Committee. So, this slide briefly describes the roles of each of those groups. And I'll speak to those roles a little bit more as I walk through

the methodology.

But, briefly, our NESR staff are really scientists with systematic review methodology experience. And so, we'll be handling all aspects of planning, facilitating, conducting, and then, of course, documenting the work necessary to complete your systematic reviews in accordance with our methodology.

You, as the Advisory Committee, are really the scientific experts with that diversity of expertise and experience who will work with our staff to help us refine and provide feedback on various systematic review materials, like analytic frameworks, inclusion/exclusion criteria, and then, of course, play a very critical role in synthesizing the body of evidence to answer important diet-related questions that you've been tasked with answering.

In addition, as Dr. Stoody mentioned earlier today, too, the Advisory Committee will do its work in subcommittees. Each subcommittee conducts its work in between meetings of the full

Committee, and then, will provide updates for deliberation and discussion at subsequent public meetings.

All right. So, getting into the process, we begin the systematic review process by working with the subcommittees to develop an analytic framework for each of the questions that you'll be answering using a systematic review. The analytic framework really defines the core elements of the systematic review question. So, it defines the population of interest, the intervention or exposure, as well as what it's being compared to or the comparator, the outcomes of interest. It also defines key terms and identifies factors such as key confounders and other critical factors that could be impacting the relationship being examined.

So, the analytic framework, I would say, really is sort of the foundational part that defines how the rest of the systematic review will play out. It informs not only the inclusion/exclusion criteria, as well as the

literature search strategy, but it defines what data will be extracted. It informs risk-of-bias assessments, and then, of course, it drives the strategy for how you will synthesize the evidence to draw conclusions and grade the body of evidence. So, this is really a critical part of the process.

Next, NESR staff will facilitate your use of the analytic framework to establish inclusion and exclusion criteria upfront before any studies have been reviewed. These criteria are tailored specifically to each of the individual systematic review questions, and they're really designed to guide a very objective and consistent and transparent identification of the most relevant and appropriate studies to be including in the systematic reviews.

And again, the criteria are also framed to ensure that the reviews are useful for informing U.S. federal guidance. And so, whenever possible, we're including studies that are applicable to the U.S. population, are

informative to our federal nutrition policies and programs, and then, of course, are most rigorous from a scientific standpoint.

And as I mentioned, the criteria are tailored specifically to each of the systematic review questions, though we do have a number of standard criteria that we typically apply consistently across our reviews, unless there is a very strong rationale to do otherwise. And so, I've put them here on the slide, and I'll walk through each one and just talk briefly about those criteria.

First is study design. We include the designs that offer the strongest evidence to support a relationship between diet and health. So, obviously, randomized controlled trials are on that list as well as non-randomized controlled trials, but we also do include prospective and retrospective cohort studies, as well as nested case-control studies, which means that we do exclude typically uncontrolled trials as well as cross-sectional studies and case-control studies.

And so, while we do acknowledge that relying on RCTs is really important, we also believe that, by including high-quality, rigorously-conducted observational research, it can really provide an important complement to the evidence provided by the RCTs, and allows us to look, for example, at research done in more vulnerable populations -- for example, the pregnancy and birth to 24 months population is a good example there -- or to look at longer-term or more rare health outcomes.

In addition, though, our process does have several steps later on, and I'll note those as I go, where we really take study design into consideration and really weigh the strengths and limitations of the various designs that were being reviewed.

So, next is publication status. We include peer-reviewed publications and exclude gray literature or unpublished literature. I think this is a good place to note that we do address publication bias later in the process

during the synthesis process, and we do, also, take steps to ensure that we're not including any articles published in predatory journals, which are those journals that don't have very good peer-review policies in place. And then, we're also ensuring that articles that have been retracted are not considered.

We also include studies published in English and exclude those published in languages other than English. And then, when it comes to country, again, because our focus is on looking at evidence that's most generalizable to the U.S., we do include studies conducted in countries that -- we use what's called the Human Development Index, which takes a number of different factors into account, like life expectancy, standard of living, education level. It ranks countries according to that criteria. And then, we include studies that are done in countries ranked high or very high and exclude those that are done in medium- or low-ranked countries.

And then, finally, health status of study subjects is another critical one. As you've heard a few times today, the Guidelines really focus on health promotion and disease prevention, and our not clinical guidelines for treatment of individuals with a specific condition or a specific disease. And so, therefore, we really aim to include studies that are done in a population of subjects that are healthy or at risk for chronic disease.

We'll also include studies that enroll some of a population that may be diagnosed with a disease or that has the health outcome of interest, but we do exclude studies where they exclusively enroll individuals with a disease or with the health outcome of interest because that tends to be more of a treatment paradigm. So, looking at diet or nutrition as a way to treat a disease versus using it or examining it more in sort of that disease-prevention/health-promotion paradigm.

And so, at the bottom of the slide

there are some examples of other criteria that we would establish, things like the date of publication, how the intervention or exposure was defined, what the comparator is, and then, what those intermediate and long-term health outcomes are. And there may be other criteria that you would consider establishing just based on whatever question it is you're answering.

So, next, our NESR librarians will create what we call a search strategy. They use the analytic framework and they use that inclusion/exclusion criteria as their guides. And the goal is to find all of the studies that are relevant to the question you are addressing.

And so, the strategy identifies both the relevant electronic databases -- we always search PubMed; we always search Cochrane and Embase. We may consider additional databases that may be appropriate for whatever topic is being addressed. And then, we also identify key terms that are used in each of those databases to search for the types of studies that we're

looking for.

And so, you will have an opportunity to review that search strategy, and we do have a process where it's peer-reviewed by another librarian as well, just to make sure that it's comprehensive in capturing all of those key search terms to identify the studies that we would be looking for.

So, once the search strategy is finalized and approved, the librarians will conduct that search. And that yields a pretty long list of potentially-relevant articles, but our goal here is to really cast a very wide net and just make sure that we've identified any potential article that could be relevant for inclusion in the review.

So, the next process is screening all of those literature search results. We have two NESR analysts who will independently screen all of the studies that were identified in the librarians' search using the inclusion and exclusion criteria. And we do this using a web-

based tool, which really helps make the process a little bit more efficient.

But the goal here is to review every single one of those studies that came up in the literature search against those criteria and exclude any that do not meet the criteria. And so, ultimately, this means that only those studies that meet all of the criteria will be included in the final systematic review.

We also do a manual search here, which is a very standard step in conducting a systematic review. For us, it involves searching all of the reference lists of the included articles that we've identified, just to make sure that we haven't missed any peer-reviewed article that might meet our criteria, but wasn't picked up in the electronic database search.

It's very rare that we would pick up an article this way, but sometimes there are problems with how a paper was indexed in PubMed, for example, and we could have missed it. And so, really, this is just a way to make sure that

we're being as comprehensive as possible in picking up any possible article that might relate to the question that's being addressed.

And then, our NESR analysts will document all of the search results, including that list of included articles, and a list of all of the articles that were excluded with the rationale for why they were excluded. So, this process of both searching and, then, screening the literature is really a very systemic and well-documented process, and it's really based on objective criteria. And so, ultimately, it should be reproducible and clear as to why we've included some studies, and then, if we've excluded studies, it's clear as to why they were excluded as well.

So, next, our NESR analysts will extract key data from each of the studies included in the systematic review. And the subcommittee members will provide input onto what data should be extracted, just based on what kinds of information you think you would need to

answer the systematic review question.

We also do harness the power of technology here as well. Using a web-based tool really helps us with accurate, consistent, and efficient data extraction.

And then, once that's complete, our NESR analysts will also use that information to create a series of evidence tables, which are essentially ways to summarize and describe the body of evidence, and will be useful to you all as you move into this step of synthesizing the evidence to draw conclusions.

In addition, conducting a formal risk-of-bias assessment for each of the included studies is another critical part of our process. I've included a definition here on the screen for what risk of bias is. It's the likelihood of a systematic error or deviation in the results or inferences of a study which could lead to under- or overestimation of either the true effect of the intervention on the outcome or the association between the exposure and outcome that

you're looking at.

And so, this assessment really is designed to provide information regarding each of the included studies, as well as the body of evidence as a whole, that can be considered when synthesizing the evidence, drawing conclusions, and, of course, grading the strength of the evidence.

So, this is one area of systematic review methodology that has been evolving quite a bit in recent years. We've really been following these evolutions closely and have decided, in order to align with some of the other systemic review organizations that are out there, to adopt the three tools shown on this slide here to assess risk of bias in the reviews that you'll conduct as the 2020 Committee.

So, the first is called Cochrane's Risk-of-Bias Tool for Randomized Trials, or Risk of Bias 2.0. This is a relatively-new tool released by Cochrane and, obviously, focused on randomized trials.

The next tool is also a Cochrane tool. It's called the Risk of Bias in Non-Randomized Studies of Interventions Tool, or ROBINS-I. And that is a tool to assess risk of bias in non-randomized trials.

The last tool is one that we have adapted for use in our work. There is not a universally-accepted tool right now for assessing risk of bias in observational studies. We have been involved in an effort that Cochrane is leading to do this in collaboration with some other U.S. federal entities, but they haven't released a final tool yet. They have released a preliminary tool, however. It's based very closely on the ROBINS-I tool. And so, we have taken that preliminary tool and adapted it for use in assessing nutrition research.

And so, the types of bias, the tools, you can get a general sense of the types of bias these tools will be considering in the list at the bottom of the slide. And then, I'll also just note that our website has these three tools

linked on it, as well as there's a website for the Cochrane tools that provides extensive information about the tool and the guidance for answering the questions.

So, next, the subcommittees will use the extracted data, the evidence tables, those risk-of-bias assessments from all of those included studies to examine whether or not the intervention or exposure that you're looking at is related to the outcome in the population of interest. So, coming back to that analytic framework and really thinking about how the evidence addresses the question as you've laid it out in the analytic framework.

And so, in essence, evidence synthesis is the process by which evidence from multiple studies is described, compared, and then, combined qualitatively. It really focuses on looking for overarching themes in the evidence. It looks for differences in how the studies were conducted and their results. Looks for factors that may have been impacting the relationships

that you're examining, and then, of course, identifies gaps and limitations in the body of evidence as well.

So, next, the subcommittee members will use the evidence synthesis to develop a conclusion statement. A conclusion statement is a summary statement that reflects the complete body of evidence reviewed. So, it doesn't take into consideration evidence outside of those included studies that you have included in the review. And it's really written as an answer to the systematic review question.

In addition, it may also state when there's not enough evidence to answer the question as well. So, it's either an answer to the question or a statement that there is not enough evidence to answer the question.

So, next, once you have a conclusion statement in place, you'll use predetermined criteria to assign a grade to the evidence underlying that conclusion statement. And the grade really indicates kind of the strength of

evidence underlying that conclusion or how confident we are in the conclusion statement. I'll talk a little bit more about the predetermined criteria on the next slide. But the goal is to really consistently and transparently assess the body of evidence to assign one of the four grades that are listed on this slide.

So, when you indicate a strong grade for a conclusion statement, that really means that there is strong evidence underlying that grade, such that if new articles are published, it's probably not going to impact the conclusion that you've drawn.

When you move to a more moderate sort of strength of evidence, it's sort of reflective of the fact that, if new articles are coming out, you might need to make some edits to that conclusion statement.

And then, finally, a grade of limited indicates that the body of evidence was much more limited in nature, and if new studies are

published, that will most likely need some updates and edits to it.

And then, finally, we do have a grade not assignable option, and that's really to indicate where a conclusion statement was not able to be drawn, either because there was no evidence available to answer the question or there was some evidence, but it was very limited in nature and had many limitations in the body of evidence.

So, grading is another area in the systemic review field where there has been quite a number of advancements over the last several years. NESR has made some updates to leverage those advancements. Specifically, we have updated our grading criteria to align more closely with a very commonly-used grading approach called GRADE, although we do have some points of differentiation really to meet the purposes of what a NESR review is intended to be used for.

So, NESR's grading process, very much

like GRADE, provides a very structured and transparent approach for assessing the strength of the body of evidence. And we do have four out of the five grading elements in common. Risk of bias, consistency, directness, and precision are the four elements that we do have in common.

GRADE has a fifth element for publication bias, which, as I mentioned earlier, is something that we acknowledge as being very important to consider. However, GRADE acknowledges, as well as we do, that there's not really great gold-standard methodology for assessing publication bias, particularly when it comes to observational studies. And so, we have elected to not include it formally in our grading process, but to consider it thoroughly during the synthesis process and address it in describing the body of evidence.

On the other hand, our fifth criteria for grading is generalizability. And so, because our reviews are being so directly used to inform federal policies and programs, directly impacting

the American population, we've really felt that it was imperative to make sure that we were considering how generalizable the body of evidence was to the American population of interest. And so, for this reason, we've retained generalizability as a grading element for use in grading our conclusion statements.

Finally, I think this is another really important place in the process where we take study design into consideration. These criteria shown on the slide will be assessed separately for each category of study design -- this is also very similar to the way that GRADE works -- before an overall grade is finally assigned to the complete body of evidence. But this really will allow for consideration of the strengths and limitations of the various study designs that have been included, particularly when a body of evidence includes a mixture of randomized controlled trials and observational studies.

And there's just a note at the bottom

of the slide that our grading rubric also, which spells out the criteria that are seen on this slide here in much more detail, is available on our website.

And then, finally, throughout the process of conducting a systematic review, many gaps and limitations are identified. And therefore, as a final step, the Committee should make recommendations for future research that may address any of the gaps and limitations that emerged as you reviewed and synthesized the body of evidence.

So, that's really the overall process that we use for conducting a systematic review. I'm going to switch gears really quickly just to talk a little bit about our methodology for using and/or updating existing NESR systematic reviews.

As Eve mentioned, we have done a number of systematic reviews that are potentially relevant to the questions that you'll be addressing, that you've been tasked with addressing. And so, we'll work closely with the

subcommittees to identify any relevant existing NESR systematic reviews that we've done that are very similar in nature to the question that you're addressing.

In terms of relevancy, we're looking for things like it was done in the same population. It's looking at the same diet-related intervention exposure. It's looking at the same outcomes. It used similar definitions for key terms, and it used the same inclusion/exclusion criteria.

If a relevant systematic review is identified, our next step will be to take a look at whether or not it's timely. And by that, we mean taking a look at the date range that was used in the original systematic review and determining whether it was recent enough to be used or if it would require some updating.

And so, if an update is needed, we will conduct another literature search, do thorough screening of those articles, and identify any relevant research articles that may

have been published after the completion of the original systemic review. And then, of course, sort of take them through the same process I just outlined in terms of extracting data and assessing risk of bias.

We'll also during this process take some steps to determine whether any of these existing systematic reviews may have included an article that has since been retracted. So, that's something that we'll cover our bases on.

So, next, the Committee can then proceed with using the existing review to answer their question. If an existing review is being used and not being updated to answer a question, you can carry forward the conclusion and the grade from that review. If an existing review is being updated, you can consider that new evidence that's been identified since the completion of the original review and really sort of consider that in relation to the body of evidence that was originally reviewed and the conclusions that were originally drawn to determine whether any updates

or changes to the conclusion or grade would be warranted.

And then, finally, just a few slides to talk about our core values around transparency and accessibility, and really making the work that we're doing as transparent and accessible to a wide range of audience as possible.

So, to correspond with our new name, we've launched an updated website, nesr.usda.gov, as listed at the top of the slide. I would just say don't put "www" in front of that because it won't work. Just go straight to nesr.usda.gov. And that website still contains all of the complete documentation of every review that we have done previously. So, all of the reviews, for example, that were done by the 2015 Committee are available on that website right now.

We've also included a number of enhancements to the website, really designed to improve the user's experience. There's a lot more information about our methodology. There's an animated infographic around the methodology,

for example, which you've sort of gotten a taste of in the presentation today. We've done some mobile and search optimization, and we've tried to use plain language throughout, wherever possible.

Another key change that we've made is that we do plan to make the work transparent sort of as it's ongoing by posting our systematic review protocols on dietaryguidelines.gov. In a section of the website shown here in the screenshot called "Work Under Way," there will be sort of updates as to the status of each of the questions that are being addressed. And then, there will be the full systematic review protocol posted for each of those questions as your work gets underway and continues.

And so, the protocol really is sort of that plan for how the systematic review is being conducted. And it will include the analytic framework, the inclusion/exclusion criteria, the search strategy. And then, once we do the search and screen the results, we'll also update to

include the list of included articles as well as the list of excluded articles with the reason why they were excluded.

And then, finally, much down the road, as you start to draft conclusion statements and grade the evidence, those will be added to the website as well.

So, we do encourage everyone, both on the Committee but mainly the audience here, to really regularly check dietaryguidelines.gov to follow along with the Committee's work.

And that's where I'll stop today, but I'm more than happy to take any questions that you might have about the process.

(Applause.)

VICE CHAIR KLEINMAN: Julie, that was terrific. Thank you very much.

Just a couple of questions. Heterogeneity of studies, does that fit into the bias group? Is that where you consider that or?

DR. OBBAGY: Yeah, I would say that heterogeneity, obviously, is an issue that does

come up. That's something that you'll weigh in both your synthesis process and drawing conclusions about the body of evidence. I mean, that's really looking for both the similarities and differences, not only in how the results are being reported, but how the studies were conducted as well, the populations they're done in. So, you really need to kind of consider all of that as you're synthesizing the evidence. But we don't have sort of like an assessment tool or anything to get at heterogeneity, but that's really kind of what the synthesis is intended to get at.

VICE CHAIR KLEINMAN: Have you considered using -- I mean, there are tools to do that -- are you thinking about actually formally --

DR. OBBAGY: Yeah, we have not looked into that, but I think it's something that we could do some exploration around, because it's certainly something that is pretty common in nutrition research, in particular.

VICE CHAIR KLEINMAN: Yeah. And when you assign a level of evidence, will we be able to understand how you came to that category?

DR. OBBAGY: Yes.

VICE CHAIR KLEINMAN: Is that described for each review?

DR. OBBAGY: So, that's your responsibility really. You'll be the ones.

(Laughter.)

Yes, so, essentially, we'll get you all the evidence, but it's your job to really pull it together, draw the conclusion, and grade that strength of the evidence. So, we can facilitate that and help you along the way with our tools and our grading rubric, but that's really the core responsibility of the Committee in the systematic review process.

VICE CHAIR KLEINMAN: I should probably quit at this point, having stuck my foot in my mouth here.

(Laughter.)

But just one more brief question. How

do you deal with existing systematic reviews? So, let's say the Cochrane did a review on one of our questions of interest and they completed that in the last six months. Do you consider those or?

DR. OBBAGY: Yeah, so that's a great question. And I think, actually, there was a really good section of the NASEM report that did speak to this a little bit.

In theory, it sounds like a potentially good step to take in that it could be a timesaver. However, what we have found, and what the NASEM report also suggested, is that it can really end up being more labor-intensive sometimes than conducting the original systematic review. Because we're so focused on informing U.S. Dietary Guidelines, you know, many Cochrane reviews, while they're excellent reviews, may include research done in populations that aren't really generalizable to the U.S. And so, the work of trying to tease that apart and really kind of figure out how it fits with our purposes

can be sometimes not as easy as you would like.

And so, our focus is to really leverage the existing reviews that we've done with, for example, the 2015 Committee. We've done a dietary patterns project, the pregnancy and birth to 24 months project. So, we do have a lot of existing work that was really done very specifically focused on informing federal nutrition policies and programs in the U.S. And so, that is kind of the direction that we've chosen to go for this project.

VICE CHAIR KLEINMAN: Thank you.

MEMBER DEWEY: Thank you very much, Julie. That was great.

As you know, I participated in the technical expert collaborative for the birth to 24, and some issues came up that you were talking about today that I wanted to ask about. One of them has to do with categorizing the country in which a study was done as high or very high on the Human Development Index. And what I learned in the process is that it was being done based on

their ranking today, even if the study was done 20 or 30 years ago.

DR. OBBAGY: Yes.

MEMBER DEWEY: And so, my question is whether your tools --

DR. OBBAGY: Yes.

MEMBER DEWEY: -- now allow you to designate the HDI at the time the study was conducted.

DR. OBBAGY: Yes. Yes, we have done that change.

MEMBER DEWEY: Yes.

DR. OBBAGY: And so, we will assess the Human Development Index for a study based on the year in which it was conducted or the year in which the data were collected.

I believe the Human Development Index goes back to 1990. And so, if there were studies published prior to that, we would likely use 1990 as the year that we would assess. But, yes, we have addressed that because --

MEMBER DEWEY: Okay, great.

DR. OBBAGY: Yes.

MEMBER DEWEY: And then, with regard to generalizability, the way your slide depicted that was in terms of generalizability to the U.S. population.

DR. OBBAGY: Uh-hum.

MEMBER DEWEY: And I'm wondering if that means the average across the whole population, or is it something that this group would take into consideration in terms of whether we consider it generalizable to subgroups of the U.S.; for example, low-income subgroups?

DR. OBBAGY: Yes. Yeah, I think you can absolutely think about the general population as well as some of the potentially high-risk subgroups that may be particularly sort of impacted by a particular outcome or diet relationship. So, yes, you can sort of take that.

And then, I think when you're drawing your conclusions as well, an important step can really be to look at the populations that were

addressed in the studies you're reviewing, and as much as you can, tailor the conclusion statement to really indicate what population you think that that conclusion applies to. So, there's sort of multiple places where I think you can sort of get at that subgroup issue.

MEMBER DEWEY: Great. Thank you very much.

DR. OBBAGY: Yes, thank you.

MEMBER MAYER-DAVIS: So, I actually have two questions. One's pretty quick. I don't believe I heard you use the term "meta-analysis". So, I'm assuming that you exclude those studies and only use the primary data. Is that the case?

DR. OBBAGY: Yes, correct. So, we are really focused on doing the qualitative, systematic review of the evidence, and we haven't gotten too much into meta-analysis. A lot of the reason why is around that issue of heterogeneity, and it becomes very difficult to meta-analyze when you have such a heterogeneous body of evidence. So, that's not something we have

gotten into quite yet.

MEMBER MAYER-DAVIS: Okay. And then, my other question had to do with inclusion and exclusion criteria. I noticed that you were excluding studies that were focused on individuals with a particular disease condition, which I understand that aspect of excluding a study that was, say, only done among individuals with type 2 diabetes, for example.

DR. OBBAGY: Correct.

MEMBER MAYER-DAVIS: But I'm wondering whether you're looking at studies in which individuals were excluded if they have that condition at the beginning of, say, a prospective design --

DR. OBBAGY: Yes.

MEMBER MAYER-DAVIS: -- just being concerned that, you know, if you did such a thing, then you would end up with very healthy people, and particularly when you think about older adults, that would not actually be representative of who lives in this country --

DR. OBBAGY: Yes.

MEMBER MAYER-DAVIS: -- just because of common comorbidities that exist.

DR. OBBAGY: Yeah. No, that's a great point, that sometimes if you're only looking at the cohort, when they've excluded all of those from the get-go. And actually, that's an issue that our risk-of-bias tools really pick up in terms of selection bias. And so, while it's not necessarily usually considered as part of the criteria, our tools would pick up the fact that a study may sort of be already sort of stacked the deck to look at the healthier individuals. But I think that that's something that we can have some discussions around how to handle that kind of paper that could exclude populations like that, or not, as the case may be.

MEMBER BAILEY: Okay, I'll quickly ask my question while they're figuring out microphones.

Thank you, Dr. Obbagy.

Could you explain to me how the NHANES

and other nationally-representative survey data will be used, since currently they're in the exclusion criteria?

DR. OBBAGY: Yes. So, we typically don't -- yes, so she asked how NHANES data, studies that use NHANES data will be handled in our inclusion/exclusion criteria, based on the fact that we exclude cross-sectional studies. So, we do typically exclude a study that might look at diet in relation to health, but was done using NHANES data.

But, as I alluded to, sometimes there are questions for which a cross-sectional design is more appropriate to use. So, then, we might consider using cross-sectional. But if it's a paper looking at a diet-health relationship, it would not be included. However, NHANES will be used, and Dr. Pannucci will talk more about that in terms of your data analysis questions.

MEMBER MATTES: So, you have a number of good controls for bias. My question, and I have to admit this is a bit of a pet peeve, is,

do you control for trials where the outcome of interest was actually the primary outcome listed a priori? So often in these reviews, you get trials that, yes, I measured this and, yes, they had an outcome that's relevant. But we would never, as an original research article, viewed it as high quality because it wasn't designed to answer that question. Yet, they're included in these reviews frequently. Do you have a way -- I didn't see where in the categorization that would fall.

DR. OBBAGY: Yeah, yeah. I want to get the wording right. But there is a category within the risk-of-bias tools to look at, for example, did the study have a published protocol, both in RCT and a cohort study? And do you have concerns about selective reporting of the results, based on your review of that original protocol? So, when available, the intent is to go look at the original protocol and make sure that the analyses reported in the paper align with that protocol, and you don't have a concern

that there has been sort of some selection of results and reporting in that way.

It's a little trickier with cohort studies because they don't typically have a published protocol like an RCT might, but it's still an issue there and something we take into consideration.

MEMBER HEYMSFIELD: Where are these published? How do we find these?

DR. OBBAGY: Yes. So, they're not -- we haven't made them yet.

(Laughter.)

Again, that's sort of the work that you'll all be doing. However, our website, as I mentioned -- and it's on the slide now -- contains existing reviews that we've done before. And so, if you do go to the website, for example, there's a project section of the website; 2015 Dietary Guidelines Advisory Committee reviews are included there. And you can see all of the reviews that were done by that Committee, just to get a sense for kind of what the final product

might look like.

MEMBER BOUSHEY: Does this one work? Okay.

So, this Risk of Bias for Nutrition Observational Studies, what's classified as nutrition observational studies?

DR. OBBAGY: So, that would include things like prospective and retrospective cohort studies, case-control studies, nested case-control studies, cross-sectional study design. So, any study that has --

MEMBER BOUSHEY: So, ones that aren't included? Well, some of them?

DR. OBBAGY: Yes, it would address those, just in case we did have a review where we needed to include one of those designs, but yes. Thank you.

CHAIR SCHNEEMAN: I don't know if you're the right person to answer this question, but I am curious about other guidelines that have been developed. And it might be a particularly sensitive issue around the B-24 where they were

looking at evidence, developed a guideline. Does that information come into the information that we'll be looking at?

DR. OBBAGY: Yes. No, so we don't necessarily look at a guideline and, then, sort of backtrack to look at the evidence that was reviewed as part of it. I think we could use that as sort of a manual search source potentially to take a look back at what they may have considered, and just make sure that we've included the articles that were considered in the development of that guideline. But we do not assess a guideline or do that sort of in a systematic way as part of our process anyway.

CHAIR SCHNEEMAN: Okay. And then, I had a follow-up question on the Cochrane reviews, too. I understand your answer that sometimes picking apart what was reviewed may be more challenging than doing it. But I think where there are well-established Cochrane reviews that might have a different recommendation or a different conclusion, the Committee should be

aware of that. So, I'm wondering, do you just exclude those or do you bring that in alongside your own systematic review?

DR. OBBAGY: We don't, but that could be something that you might want to look at in sort of a contextual way and kind of compare the evidence that you've reviewed and the conclusions you've drawn when drafting your report potentially.

MEMBER MATTES: Just kind of a logistical thing. What is the realistic turnaround time? Say you present us with something, and we go, "You know, we'd really like to tweak it this way."

DR. OBBAGY: Yes, yes. I mean, we will do our utmost hardest effort to turn things around as quickly as possible. I mean, you are on a very tight timeline with the work that you're doing. And so, the staff that you saw on the slide are ready to dive in on Monday and get things really going. So, we've done a lot of work to try to prepare as much as we can for you,

but, obviously, we're really excited to get the input that we need from you all to really dive in and get the ball going. But I think we'll be turning things as fast as we possibly can as we go.

CHAIR SCHNEEMAN: Thank you so much.

(Applause.)

MS. RIHANE: Thank you, Julie, for that great overview.

So, our next speaker is Dr. David Klurfeld. He is the National Program Leader for Human Nutrition in USDA's Agricultural Research Service, or, as we call it, ARS. And he's been there since 2004. He is responsible for the scientific direction of the intramural human nutrition research conducted by USDA laboratories.

Prior to government service, he was Professor and Chairman of the Department of Nutrition and Food Science at Wayne State University in Detroit, and prior to that, was on the faculty of the Wistar Institute and the

University of Pennsylvania School of Medicine.

Dr. Klurfeld will speak today about ARS's role of peer review during this phase of the process.

Let's welcome Dr. Klurfeld.

(Applause.)

DR. KLURFELD: Thanks, Colette.

So, I've got actually very short remarks. I notice nobody's in post-prandial coma. So, glad to see that.

(Laughter.)

As you've all seen this morning, the National Academy review of the Dietary Guidelines process included recommendations to use a multi-pronged approach to strengthen what was the NEL protocol, which is now the Nutrition Evidence Systematic Review, or NESR.

As part of the Memorandum of Understanding that established the framework for agency cooperation to support the 2020 Dietary Guidelines, it included specifically calling out ARS to facilitate peer review of the systematic

reviews produced for your reference. And we will use our own statisticians and scientists in ARS playing the primary role in specific subjects, but we will also count on similarly-skilled individuals in other federal agencies, including the Economic Research Service, NIH, CDC, and FDA. We hope that will be enough agencies to facilitate the review of the numbers that Julie's group plans to do because there are more than 60 questions already on the docket for that.

But we anticipate the process to be analogous to an academic journal review. And the possible outcomes could be similar, from minor revision, acceptance, modification, or even potentially rejection. We certainly hope the latter category won't be necessary and that appropriate modifications can be done to achieve not just an acceptable review, but a high-quality review that will enable the Committee to make the best informed decision.

I want to point out some of the modifications that Dr. Obbagy's group has

instituted recently, in response primarily to the National Academy review, is using risk-of-bias assessment tools and adapting the GRADE system. And I can tell you that the group in the University of Ottawa that developed GRADE has also recently developed a system that's specifically applicable to nutrition studies. And just in the last month, I did a review for the Annals of Internal Medicine of one of their systematic reviews. And from my perspective, it looked really good. I haven't heard an editorial decision on that one yet, but that's just an aside.

So, we currently have 62 questions proposed, either by federal staff or through collection of stakeholder input. And the categories for the questions primarily are in the birth to 24 month group where we have more than 20 questions, dietary patterns where we have 17 questions. So, the bulk is in there. There's obviously huge interest in beverage consumption. So, we have about 10 there. And we have small

numbers on added sugars, types of dietary fats, seafood, frequency of eating.

So, since we have two Children's Nutrition Centers as part of ARS, we feel that we are well equipped to handle the birth to 24 month reviews.

As Julie mentioned, some of the questions may be answered with existing systematic reviews. In fact, NESR actually has proposed evaluating those reviews using AMSTAR 2, which is another formal grading system.

I can tell you that we have not fully formalized the review process. So, I'm not ready to give you any specifics of how we're going to handle a particular example. But we're looking forward to turning these around as quickly as possible. We understand the lifespan of this Committee is actually shorter than any other previous Dietary Guidelines Committee, and that's because you have more work to do.

(Laughter.)

We added two years of life plus

pregnancy and lactation.

So, if there are any questions, I will try to answer them. But that's where we are right now.

CHAIR SCHNEEMAN: So, I appreciate your setting up this peer-review system because I think it is a valuable part of the peer-review system, or the systematic review system.

Do you know, when you think about how long you would give one of the scientists to complete that, do you have a sense of how quickly they would be able to turn it around?

DR. KLURFELD: We're going to approach this just the way we do with journal reviews. I've been Associate Editor of AJCN for the last 12 years. We give reviewers three weeks. I think that's adequate, particularly if they're federal scientists. We have a little leverage on those folks. So, we're hopeful, having written a systematic review and having reviewed dozens of them, I would say three weeks is sufficient to accomplish a good quality review.

CHAIR SCHNEEMAN: And for scientists who may be familiar with the topic area, but not necessarily systematic reviews, do you have any way to provide just some background for them, so they understand what it is they're looking at and how to approach it?

DR. KLURFELD: Yes, Barbara, we've actually talked about that quite a bit, and I think we're going to have a checklist for reviewers, because our subject matter experts probably aren't going to be as familiar in-depth on performance of a systematic review. I'm sure they've all read them, but looking behind the curtain is a different story.

MEMBER BOUSHEY: So, what were you thinking of about how many reviewers for each one? Had you thought about that?

DR. KLURFELD: Oh, sure. Again, like a systematic review, simply because of the numbers -- we have 62 reviews -- I think we're going to stick with two external reviewers, and they will be anonymous reviewers, just like a

journal review.

CHAIR SCHNEEMAN: Great. Thank you very much, David.

DR. KLURFELD: Thank you.

(Applause.)

MS. RIHANE: All right. Thank you, Dr. Klurfeld.

We are just speeding right along here, aren't we?

We have a few more presentations this afternoon, but we are ready for the break. We're a little ahead of schedule, but I think because of the nature of the presentations to come, it's a good time to take a quick break.

So, sorry, everyone on the phone and here, but we will be breaking now for, let's say, 15 minutes. So, it's 10 to 2:00. So, 2:05, be back here at 2:05.

Okay. Thank you.

(Whereupon, the above-entitled matter went off the record at 1:52 p.m. and resumed at 2:08 p.m.)

MS. RIHANE: Okay. Are we about ready, everybody? All right. Great.

What I wanted to do quick, if I could remind -- we haven't really discussed this in too detail or enforced it, but folks on the phone and people who can't see who are having a hard time sometimes knowing who you are. So, if you could, when you have a comment to make or a question to ask, just announce your name. That's helpful for the transcriber as well because the meeting is being transcribed. So, they'll know, and the people on the phone can follow, and folks who can't see you will be able to know who's talking. And, you know, after a while, we'll get to know your voices and, then, it won't be so detrimental.

Okay, great. All right. So, welcome back, everyone.

Our next speaker will be Dr. TusaRebecca Pannucci. She joined the Center for Nutrition Policy and Promotion in 2015. She serves as the Lead Nutritionist for the Nutrition

and Economic Analysis team and leads a multidisciplinary team conducting analyses for the USDA Food Patterns, Healthy Eating Index, the USDA Food Plans, and expenditures on children by families. She'll be supporting the work of the 2020 Dietary Guidelines Advisory Committee and the Working Group on Data Analysis and Food Pattern Modeling, which is what she'll be discussing with you all today.

TusaRebecca Pannucci.

(Applause.)

DR. PANNUCCI: Thank you, Colette.

Good afternoon.

So, earlier you heard my colleague, Dr. Obbagy, describe the systematic review approach that will be used by the Committee to examine the relationship between diet and health. This afternoon I will be describing two other approaches presented to the Committee. Together, these approaches will be used to address the topics and questions proposed.

I do want to start by saying I'm here

as a spokesperson for the work that is really done by interagency collaborations, by federal staff, many of whom are here in the audience or on the webcast today. So, I'll be describing the data that make that analysis possible to support the questions that you will be discussing.

So, what is the purpose of data analysis for the Committee? It's a collection of analyses from nationally-representative federal data sources that will provide insights into the eating habits and diet-related chronic diseases in the United States. These analyses provide insight specifically representative of the U.S. population at each life stage.

Today, I'll share information about the federal data sources that are used in analyses provided to the Committee. A bulk of the analyses come from NHANES, the National Health and Nutrition Examination Survey. The dietary data come from What We Eat In America portion of NHANES and are supported by databases, including the USDA food and nutrient database for

dietary studies and the USDA food patterns equivalence database, both of which will be described.

I will briefly touch on other data that are used, including the National Health Interview Survey and the Surveillance, Epidemiology, and End Results Data.

The National Health and Nutrition Examination Survey, or NHANES, is a program of studies designed to assess the health and nutrition status of adults and children in the United States. And it's supported by the National Center for Health Statistics at the Centers for Disease Control and Prevention.

The goal is to develop U.S. population-based estimates of health conditions, awareness, and treatment and control of selected diseases, environmental exposures, and critical to your work, nutrition status and diet behaviors.

Findings from the survey will be used to determine the prevalence of major diseases and

risk factors for those diseases, assess nutritional status and its association with health promotion and disease prevention, and serve as the basis for national standards for such measurements as height, weight, and blood pressure.

Research organizations, universities, and healthcare providers, and educators benefit from this survey information. But, of course primary data users are federal agencies that collaborated in the design and development of the survey. The National Institutes of Health, the Food and Drug Administration, and the CDC are among the agencies that rely upon NHANES to provide data essential for implementation and evaluation of program activities.

The U.S. Department of Agriculture and the National Center for Health Statistics cooperate in planning and reporting dietary and nutrition information from the survey. These data help develop public health policy that is relevant to the U.S. population and expand the

health knowledge for the nation.

NHANES has its inception in the National Health Survey Act of 1956. This provided the legislative authorization for a continuing survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. Since 1999, NHANES has been continuously collecting data on all ages.

Data is released in two-year cycles. The most recently-released data are NHANES 2015-2016. We will be utilizing this most recently-released cycle of NHANES in analysis presented to the Committee.

But I will note that, for some analyses and subgroups of the population, multiple cycles will be combined to ensure appropriate sample size. For example, NHANES 2013-2014 will be combined with NHANES 2015-2016.

NHANES uses a complex sampling design and constructs sample weights to produce this nationally-representative data. So, data are not

obtained using a simple random sample. Rather, a complex, multi-stage probability sampling design is used to select participants representative of the civilian, non-institutionalized population. Sample weights for each two-year cycle take into account things like survey non-response, oversampling, post-stratification, and sampling error. And we apply these sampling weights and analysis to ensure the results represent unbiased estimates with accurate statistical significance.

Oversampling of certain populations is done to increase the reliability and precision of health status indicators in the populations listed on this slide.

The time between data collection and data release to the public can be explained by the rigorous data release process. All data go through quality control, editing, and cleanup. The weights must be assigned. The data must be prepared for the analyses, documentation written, and, of course, a review for confidentiality. And as mentioned, then these data are released in

two-year cycles, the most recent of which is 2015-16.

So now that we've discussed some of the logistics, let's examine the data collection. So, NHANES is unique in that it combines both interviews and physical examinations. The interview includes demographics, socioeconomic, dietary, and health-related questions, many of which are collected in the homes of the participants.

Health measurements are performed in the MEC, the Mobile Exam Centers. These equipped mobile centers travel to locations throughout the country. The physical assessment in the MEC includes things like physical exam measurements, height, weight; specialized testing, lab specimen collection, which I'll get into in a minute; 24-hour dietary recall conducted in person. And then, after the in-person exam, there are other assessments, including a second 24-hour dietary recall.

NHANES laboratory testing includes

nutritional biomarkers, diagnostic indicators for diabetes, lipid profiles, including total cholesterol, and other biochemistry profiles. These lab data allow for ongoing assessment of the U.S. population's nutrition status by measuring blood and urine concentration of biochemical indicators, such as nutrients or other dietary indicators with public health relevance.

This is the most comprehensive biochemical assessment of the U.S. population. And while these biochemical measures are useful in helping to describe nutritional status, the Dietary Guidelines provide food-based dietary guidance. So, it's imperative that we know the food and beverage choices made by Americans. From that, we use the dietary intake data from the What We Eat in America portion of NHANES.

USDA is responsible for the survey's dietary data collection methodology and maintenance of the databases used to code and process the data, and the data review and

processing.

The dietary data are collected using the gold standard for dietary assessment, a multiple-pass 24-hour dietary recall. USDA developed the automated multiple-pass method which is conducted by trained interviewers. It's a research-based approach to enhance efficient collection of complete dietary data in large-scale surveys and reduce burden on the participant.

The recall includes the quick list, which is an uninterrupted recall of foods and beverages consumed the previous 24 hours; a forgotten foods list where the interview prompts the subject for foods possibly forgotten using a standardized list of nine categories. The time-and-occasion step includes a time for the participants to add the time of day and the name of each eating event. The detail cycle includes descriptions of the foods, portion sizes consumed, and any additions. Eating occasion reviews are conducted, and they look for times

that foods might have been eaten in between the occasions already reported. And the final probe, the reviewer asks for anything else consumed, even small amounts. You can see that this is designed to help participants report their food and beverage intake in great detail.

What We Eat in America is supported by databases which provide information about the nutrient values and food group contributions of the foods reported by Americans.

FNDDS, or the Food and Nutrient Database for Dietary Studies, includes nutrient values for about 9,000 foods and beverages. These include energy as well as 64 nutrients.

The FPED, or Food Patterns Equivalent Database, converts those foods from FNDDS into food group components. The food patterns components are defined as the number of cup equivalents for fruit, vegetables, and dairy, or ounce equivalents for grains and protein foods, and teaspoon equivalents for added sugars, gram equivalents for solid fats and oils, and the

number of alcoholic drinks. The FPED database really provides a unique research tool to evaluate the food and beverage intakes of Americans compared to the recommendations in the Dietary Guidelines.

Finally, the What We Eat in America food category exists as a way to examine foods and beverages as they're consumed in the American diet. And by that, I mean we know that people eat foods in combinations. We might want to know that vegetables can be consumed on their own or as a part of mixed dishes, pizzas, sandwiches, or burgers.

So, these supporting data sources allow us to provide dietary intake analysis relevant to the U.S. population from different angles that will help answer the topics and questions presented to the Committee.

Now I'll briefly describe two other datasets. The National Health Interview Survey provides information on the health of the U.S. civilian, non-institutionalized population

through confidential interviews conducted in households. Like NHANES, this is managed by the National Center for Health Statistics of the CDC. It's one of the nation's largest in-person household health surveys, and it provides data for analyzing health trends and tracking progress towards achieving national health objectives, like Healthy People 2020. These data are continuously collected throughout the year and can be used for epidemiological and policy analysis and characterizing those with various health conditions.

The Surveillance, Epidemiology, and End Result Program is the authoritative source for cancer statistics. It's supported by the Surveillance Research Program in NCI's Division of Cancer Control and Population Sciences.

Data are collected on cancer cases from various locations and sources throughout the United States. This all began back in 1973 and has expanded to include even more areas and demographics today.

SEER collects the data and produces statistics on the trends in cancer incidence and cancer deaths. The areas where data are collected are representative of the demographics of the entire United States and cover diverse population groups. These data are used by thousands of researchers, clinicians, and cancer registrars, and can be used in analysis for the Committee.

Again, the data analysis team is a well-qualified group of federal scientists collaborating across agencies. They have advanced degrees in nutrition, statistics, and epidemiology. Many of them are listed on the slide, and we will look forward to providing analyses that the Committee can consider to answer the questions.

The data I have described will be used in analyses that can contribution to the following relevant topics and questions considered by the Committee. These have been paraphrased a bit, but across the lifespan we can

look at current dietary patterns and beverage consumption, current intakes of food groups and nutrients, nutrients of public health concern, prevalence of nutrition-related chronic health conditions, dietary intake across the life stages, relationship between frequency of eating and achieving nutrient and food group recommendations, and the relationship between added sugars consumption and achieving nutrient and food group recommendations.

We welcome you to follow along. The website that Dr. Obbagy showed earlier, shown here again on this slide, is really the go-to source for the topics and questions to be examined by the Committee. This is where you will find the protocols as they are developed, the analytic methods, and data that will be used, and then, finally, the draft conclusions down the road.

We want to emphasize our commitment to transparency and accessibility of information throughout this process.

So, I'll pause now before I talk about food pattern modeling for any questions related to data analysis that I can try to answer today.

MEMBER HEYMSFIELD: Did you say what age the NHANES goes down to?

DR. PANNUCCI: We have data on all ages in NHANES.

MEMBER HEYMSFIELD: All ages now?

DR. PANNUCCI: Uh-hum.

That was Dr. Heymsfield.

MEMBER DEWEY: So, to follow up on that, what would be the sample size of children, for example, between 6 and 24 months in the NHANES, the most recent?

DR. PANNUCCI: Sure. I don't know the exact sample size off the top of my head. The sample size is certainly smaller in those age ranges. But, by combining cycles, we can still look at estimates of food group and nutrient intake.

MEMBER DEWEY: And does that mean that the What We Eat in America information that you

described would also be available for that same sample size?

DR. PANNUCCI: Even FNDDS has information on baby foods and infant formulas, for example.

MEMBER DEWEY: But, in terms of actual consumption by whatever the survey covered --

DR. PANNUCCI: Yes.

MEMBER DEWEY: Okay. And then, I have a similar question about pregnant women and lactating women. Do you know what the sample size for those was?

DR. PANNUCCI: I don't have the sample sizes memorized, I'm sorry, but those will be a part of our conversation. And overall, this is a new piece to examine. So, we'll definitely want to have conversations around the limitations and strengths of the information that we can obtain using NHANES.

MEMBER DEWEY: Okay. And I forgot to identify myself. This is Kathryn Dewey.

DR. PANNUCCI: Thank you, Dr. Dewey.

MEMBER SABATE: Hi. My name is Joan Sabate.

And I was going to ask the same as hers, sample size for some age groups. But let's now move onto sample size for some of the minority groups, such as Asians, for instance. You say that NHANES also covers Asians or Hispanic?

DR. PANNUCCI: Uh-hum.

MEMBER SABATE: But you have about 5,000 in total?

DR. PANNUCCI: So, we use the survey weights to ensure the national representativeness of the populations. We'll have to get that data breakout for you. I don't have it memorized.

MEMBER SABATE: Okay.

MEMBER VAN HORN: It's great to see the -- oh, sorry, Linda Van Horn -- it's great to see the movement towards understanding eating patterns and food groups, and things of that sort. But I am wondering, because I don't know, to what degree the availability of food

processing, brand names, fast food consumption, things like that are built into the database now.

DR. PANNUCCI: Sure. I can speak to that briefly, and we can get into it in more detail. But USDA does have the Branded Foods Database, and there's a lot of work going on around that, although it's not integrated into NHANES.

As far as things like fast food, there are questions about the location of the food consumed. So, we can look at things like food away from home, uh-hum.

VICE CHAIR KLEINMAN: Ron Kleinman.

When will the '17-18 data be available? Because the challenge here is that, for '15-16, by the time this comes out, we're already a decade behind in at least that data.

DR. PANNUCCI: That's a great question.

VICE CHAIR KLEINMAN: Yes.

DR. PANNUCCI: That's a great question, and we've talked about this as a team.

VICE CHAIR KLEINMAN: Can we get a special deal on this?

(Laughter.)

DR. PANNUCCI: Well, if the data angels could come and make all of the databases ready.

The issue is that the data will be starting to be released towards the end of the deliberation process or beginning of the writing process. Things like the FPED database, that's not released until a little bit later. So, it is that data release process that I described that translates to that difference in the time that the data are collected, which is ongoing now, and the time that it would be able to be used for the Committee. So, the '17, sorry, the '15-16 is the complete package of data and supporting databases that will be able to be used by the Committee.

VICE CHAIR KLEINMAN: So, in line with that, we're talking about federal databases.

DR. PANNUCCI: Yes, sir.

VICE CHAIR KLEINMAN: Is there any

opportunity to use, let's say, an industry-sponsored database? I think for the population of birth to two, there is the FITS study, for example, and that's all published. And some of it's duplicative, but some of it actually complements what NHANES is collecting. Is there any opportunity to take advantage of what's published?

DR. PANNUCCI: We will be providing sources from the federal datasets for the Committee.

VICE CHAIR KLEINMAN: Only the federal datasets? Okay. Thank you.

CHAIR SCHNEEMAN: This is Barbara Schneeman, and I have two questions.

One is I notice in your relevant topics and questions you refer to the nutrients of public health concern. And I think it was mentioned in an earlier presentation that the federal government is moving to a more standardized definition of nutrients of public health concern. Is that something you can share

at this point?

DR. PANNUCCI: No, we're going to be talking about that at a future meeting in detail, uh-hum.

CHAIR SCHNEEMAN: Okay.

DR. PANNUCCI: Yes.

CHAIR SCHNEEMAN: Okay. And then, again, this may be a future meeting question, but I think in Dr. Stoody's presentation she showed that there was a slight tickup in the Healthy Eating Index. And do you have a sense of what caused that slight uptick?

DR. PANNUCCI: Tomorrow you will hear the state of the American diet.

(Laughter.)

And I will be presenting data on that. So, stay tuned. I'm sure that's a real kind of -- I'm losing the words -- but that's the trailer for tomorrow.

(Laughter.)

So now, we'll have even more people staying tuned to find out not only the Healthy

Eating Index, but drilling down into data behind that. And I'm excited to share that tomorrow, yes. But I do have ideas.

I will say, in preparation for tomorrow, that it is the different levels of data that I described today that allow us to drill down and start to look what might be behind that main number.

CHAIR SCHNEEMAN: So, coming back to Dr. Kleinman's question about the published data from the FITS study, I'm wondering, does that somehow work its way into what we heard earlier on the systematic reviews? Is there a way that that might be looked at in that context?

DR. PANNUCCI: Right, the cross-sectional studies are excluded, uh-hum. Yes, the cross-sectional studies would not come up in the systematic reviews, no.

MEMBER MAYER-DAVIS: Yes, Beth Mayer-Davis.

So, really just to follow on this conversation, you know, in terms of the data, so

you indicated that you would be using the federal databases and described those. And we have this question about FITS, which just made me think, well, if there's an NIH-sponsored grant, those data are the data of the American taxpayers, and if there's an appropriate database that's been posted onto the NIH repository for the Institute, might not those data be available, if there's something otherwise missing that is critical?

DR. PANNUCCI: I think that's an interesting question. Maybe we can have a bigger discussion around that. But, as the data analysis team, our plan is to be using the federally-available datasets.

CHAIR SCHNEEMAN: Okay, great. Thank you.

DR. PANNUCCI: Okay. Does anybody need to quick stand up, sit down, a quick stretch break? Because you get to hear from me again.

(Laughter.)

(Applause.)

All right. Well, thank you very much.

And now, it's my pleasure to talk to you about food pattern modeling. So, food pattern modeling, along with the NESR systematic reviews and data analysis, provide insight to answer questions from different, but complementary angles, which you've heard about before. So, this presentation describes both the USDA food patterns and the food pattern modeling process.

Food pattern modeling is an analysis approach used to understand how changes to food group intakes might impact meeting nutrient needs across the U.S. population. Because the Dietary Guidelines provide food-based recommendations, it's imperative that the Committee be able to articulate the evidence on the relationships between diet and health through food patterns that might be adopted by the American public. And food pattern modeling is the approach that can help us answer such questions.

To understand the modeling approach, it's helpful to have an understanding of the USDA

Food Patterns that serve as the foundation to this modeling, to food pattern modeling. USDA has a long history of providing food-based dietary guidance represented by the images of food guides shown here. Dating back to the early 1900s, there was a focus on protective foods, and then, to a foundation diet for nutrient adequacy with daily number of servings from seven food groups in the 1940s. By the late '70s, there was guidance on moderating intakes of fats, sweets, and alcohol, and the total diet approach was well-established with goals for adequacy and moderation by the early '80s. This guidance has evolved over time, of course, to reflect the available science and most recently reflects the 2015-2020 Dietary Guidelines for Americans.

The USDA Food Patterns were developed to help Americans carry out the Dietary Guidelines for Americans. So, therefore, the Food Patterns provide examples of food group amounts designed to promote health and meet nutrient needs. Again, they articulate the

evidence on the relationship between diet and health, and we compare those patterns to dietary reference intake nutrient recommendations developed by the National Academies.

USDA Food Patterns are based on a range of foods consumed by Americans, but in nutrient-dense forms of those foods. In other words, foods prepared with minimal amounts of sodium, saturated fat, and added sugar. The Food Patterns are examples and use broad food group amounts, which makes them adaptable to fit an individual's preferences. Those preferences might be cultural preferences, preferences related to an allergy or intolerance, or budget constraints.

The Healthy U.S.-Style Pattern, published as part of the 2015-2020 DGAs, as shown here, to illustrate a few points that I assure you can be made without you needing to read all of the numbers.

(Laughter.)

Briefly, the pattern describes the

amounts and types of foods to consume through the recommended intakes for five major food groups and subgroups within several of those food groups. So, fruits, vegetables, and within vegetables, dark green, red-orange, beans and peas, starchy vegetables, and other vegetables. Grains is broken down into whole grains and refined grains. Protein foods, and then, meats, poultry, and eggs, seafoods, and nut, seeds, and soy products. And then, dairy foods, oils, and a limit on calories for other uses.

All amounts are given in cup or ounce equivalents, with the exception of oils in grams and calories for other uses, which is given as an absolute number of calories that can be converted to a percent of total calories within the pattern.

Recommended amounts and limits in the three USDA food patterns that were a part of the 2015-2020 Guidelines are included for 12 calorie levels ranging from 1,000 to 3200 calories. The patterns at 1,000, 1200, and 1400 calories were

intended to meet nutrient needs of children ages 2 to 8, and patterns at 1600 calories and above were intended to meet the needs of those 9 years old and older. Of course, individuals should follow a plan that meets their estimated calorie needs.

So, it's the structure of the food patterns that allows for modifications that test the overall influence of hypothetical changes to dietary recommendations. So now that we have a foundational understanding of the patterns, we can better understand the food pattern modeling approach used to answer the proposed topics and questions for the Committee.

So, what is food pattern modeling? Simply put, it's the modification of USDA Food Pattern food groups, an assessment of their impacts on nutrients within the patterns. It's a way to answer questions about hypothetical changes to food-based recommendations.

Generally, the analyses involve identifying the impact of specific changes in

amounts or types of food that might be included in the pattern. It's not menu modeling, which specifies particular foods and would be prescriptive.

Staff at CNPP, the Center for Nutrition Policy and Promotion, and Committee members recognized that the food groups and nutrient profiles in the USDA Food Patterns presented an opportunity for an innovative and a creative approach to solve some hypothetical questions back in 2005.

The food pattern modeling methods were initially developed for that 2005 Committee when the Committee was asking "What if?" questions to staff. Over time, we've increased the capacity of the method to answer questions by the Committee. And by 2015, the Committee came with the expectation that food pattern modeling would be a source of evidence to consider, and it remains a cross-cutting topic for you all.

Here's an outline of our current process. You could say that it's really already

begun because the topics and questions that will be addressed have been identified and have already been listed on dietaryguidelines.gov.

Supporting staff will work with you, the Committee, to discuss the planned approach and develop a protocol for answering each of the questions. You will find these questions on the topics and questions tracker that has been mentioned several times by Dr. Obbagy and myself.

Then, staff will modify the appropriate food patterns elements, which I'll describe in just a minute. And then, we'll apply those modifications and calculate the nutrients in the pattern across the calorie levels and compare to the DRIs. This is done to examine the nutrient adequacy for the different age-sex groups for which the different calorie levels might be appropriate. Finally, after the analysis, the draft conclusions will be posted online.

So, what are the modifiable elements of the food patterns? I mentioned previously

that the structure of the patterns with the food groups and subgroups allows for elements to be modified as part of the modeling process. And there are four elements that can be modified. The food group amounts in a pattern can be increased or decreased. Certain foods can be introduced or excluded entirely; for example, in a vegetarian pattern. And the goals and constraints can be modified. For example, we know that there is new DRI for potassium. So, we would apply that in our list of goals and constraints. And last, the food group nutrient profiles, which are the average nutrients of foods consumed by Americans in nutrient-dense forms, can be adjusted.

In thinking about food pattern modeling, there are two key assumptions that really need to be kept at front of mind. We assume population-based consumption patterns. We're really implementing foods reported by Americans, but in their nutrient-dense forms. And this allows us to articulate the evidence in

a way that could be adopted by the American public.

We also assume compliance with all food intake recommendations when examining whether nutrient needs have been met. Of course, we cannot predict the behavior of individuals.

So, here's a paraphrased list of the relevant topics and questions that will be addressed using food pattern modeling. Relative to the B-24 population, can a pattern be established based on the relationships identified in the systematic reviews? Again, based on the relationships identified in systematic reviews, are there changes to current food patterns that are needed? Do the patterns meet nutrient recommendations for each stage of life through variations of the patterns? Is there evidence to support supplementation and/or consumption of fortified foods to meet nutrient adequacy? And what is the relationship between added sugars consumption and achieving food group recommendations?

Again, I'd like to acknowledge that this is a team effort. My team at the Center for Nutrition Policy and Promotion includes well-qualified individuals with advanced degrees in nutrition and statistics. Kristin Koegel, Kevin Kuczynski, and Cheyenne Swanson, all of whom are here today, will be working to support you in answering these types of questions.

I can't emphasize enough our commitment to transparency and accessibility of information. Again, I invite you all in the audience to follow along in the topics and questions to be examined by the Committee in the "Work Under Way" section on dietaryguidelines.gov. Here you'll find the protocols as they're developed, the modeling methods, and the draft conclusions.

And with that, I will again open it up to questions from the Committee.

Dr. Mattes?

MEMBER MATTES: Thank you. Very good.

So, you've discussed your ability to

look at patterns in terms of nutrients in foods, but, of course, there are circadian, infradian, seasonal, cultural, lots of different kinds of patterns. Can you work on those as well? One of our questions has to do with eating frequency.

DR. PANNUCCI: It does have to do with eating frequency.

MEMBER MATTES: That kind of data would be valuable.

DR. PANNUCCI: That would be an interesting discussion to have. That's not something that has been addressed in the modeling, but that's a discussion that we could have.

CHAIR SCHNEEMAN: This is Barbara Schneeman.

I would assume that part of that question probably goes back to the data that we have from NHANES or from something else.

DR. PANNUCCI: Yes. Right. And in NHANES, there is the time of day-occasion that can be examined. Typically, the food patterns

really look at daily amounts to consume, but don't assign patterns related to things like time of day.

MEMBER DEWEY: This is Kay Dewey.

DR. PANNUCCI: Yes?

MEMBER DEWEY: So, for the birth to 24 age group, we don't already have an existing guidelines in terms of the food groups and amounts?

DR. PANNUCCI: That's right.

MEMBER DEWEY: So, can you do this backwards? Can you start with meeting nutrient needs and work backwards to dietary patterns that would achieve those? We tend to do that using linear programming.

DR. PANNUCCI: Uh-hum, I'm familiar with the programming. We use that for other projects.

MEMBER DEWEY: But I'm not sure if this particular technique could be reverse-engineered.

DR. PANNUCCI: I mean, if you're

thinking about linear programming, like an optimization model, that's something that could be explored. Our team does use those optimization models in a different project, but we have not used optimization modeling for the rest of the patterns. I think some of it will depend on the evidence from the systematic reviews, and that will also need to be considered when discussing that overarching question.

MEMBER DEWEY: Thanks.

MEMBER SABATE: Joan Sabate.

DR. PANNUCCI: Yes?

MEMBER SABATE: I'm very happy that this tool is available to us, I mean at least analyzing the situation in the U.S. population and being able to make recommendations. Based on what you mention, if I've understood correctly, you have the ability to use nutrient data that comes from food patterns and see in different groups or subgroups of the U.S. populations, whether by age, by culture, by whatever, I mean by modifying some food groups, we still can

accomplish the nutrients of the DRI.

DR. PANNUCCI: Uh-hum.

MEMBER SABATE: I think this is one step and it's useful, but I think the purpose of this Committee -- and that is not a question to you; it's also a reflection for the Committee -- I think the purpose of this Committee is going beyond to meet the DRI. It's to try to develop a pattern, I mean, that goes towards optimal nutrition. But that is going beyond the growth and development and reproduction, and going to lowering the risk of disease, longevity, so on and so forth.

So, for this, it's going beyond the published nutrient recommendations, and we are going into phytochemicals, phytosterols, I mean, and many other compounds that are not nutrients and they do not participate in any of the metabolic classic describing patterns.

So, how can you help us in accomplishing that? So, I mean, given a set of compounds present in the foods that sometimes we

don't even know the exact composition, I mean, and having outcome longevity and, you know, low risk for chronic disease, how can we fit into this model?

You know, it's going from nutrient adequacy to optimal nutrition. That's what I'm basically -- because I think that is ultimately the purpose of this Committee. It's not to meet DRI. This is another committee at the federal level.

DR. PANNUCCI: Does the Committee want to discuss that?

(Laughter.)

Yes, that's an interesting question, and we do think about the patterns being food groups, food group amounts that reflect patterns that are associated with positive health outcomes in the population, so things we do see in systematic reviews and how that feeds into the conversation around food pattern modeling.

And the other would be understanding whether any of those phytonutrients might be

available in the FNDDS database, and I don't remember exactly which ones are available.

CHAIR SCHNEEMAN: I think maybe related to that question, I'm looking at your modifiable elements. And several people have referred to cultural aspects. And yet, we have foods reported by Americans in nutrient-dense form, which kind of homogenizes us down to some very basic foods. And I know that the Academy committee was concerned about that; that we wind up with a generic food pattern as opposed to reflecting more cultural-ethnic food patterns that could also be structured to meet the Dietary Guidelines. And I'm just wondering how far the Committee can go with this approach to try and consider some of those issues.

DR. PANNUCCI: I think food pattern modeling can be used to look at patterns that have been shown to have positive health outcomes in the literature. So, some of that conversation -- again, I keep referring back to, what does the science say and how do we want to examine that as

it applies to the U.S. population through food pattern modeling? So, I think that would be a great conversation to have, to see if that's something that we want to continue to look at through food pattern modeling.

CHAIR SCHNEEMAN: I guess a part of my question is, you know, for example, the Dietary Guidelines, the 2015 did include Mediterranean diet.

DR. PANNUCCI: Yes.

CHAIR SCHNEEMAN: It included vegetarian diet. I can't remember others. But if someone is coming from more of a Hispanic focus or more of an Asian focus, is it our job to be thinking about how would we modify what's within the food groups or is that something that happens after the Committee makes its recommendation? Where does that happen that we start to apply it to different approaches that people might use to build their diet?

DR. PANNUCCI: Well, the patterns as they are are fairly adaptable within the food

groups. But, to your point earlier looking at some of the demographic subgroups, we might want to look at data to see how similar or different their dietary patterns are as well, to drive the differences in food group amounts in a pattern.

All right. Well, thank you. I'm looking forward to future conversations with all of you.

(Applause.)

DR. STOODY: All right. Thanks, Dr. Pannucci.

Okay. So, we are running ahead of schedule, but we will -- I don't think this will take an hour and a half -- but we will continue today with our closing out. And we want to talk a little bit, as we close out, about opportunities for public engagement.

There are multiple opportunities for the public to participate in this process that began before this Committee was established, but during the Committee's review of the evidence and, also, after the Committee's review of

evidence. And we want to talk about each of those just for a few minutes.

First, there were two key opportunities for public input before this Committee was established, and you've heard about that quite a bit today. That was in the establishment of the topics and scientific questions. So, as was noted, for the first time the Departments proposed topics and scientific questions to be examined by the Committee, and then, we had a public comment period. Over 12,000 comments were received on the topics and questions, and we did that about a year ago. And then, the topics and questions were refined based on that public and federal agency comments. And Janet de Jesus will give more information about the specific topics in that refinement in a presentation tomorrow.

Also, with Committee nominations, all nominations to the Committee were from the public. So, everyone here as a part of this Committee was somebody who was nominated from the

public. Nominations were accepted. We had a 30-day nomination period from September 6th to October 6th and had wonderful nomination pool and really excited to have this opportunity to bring this Committee together.

During the Committee's deliberations, as we have noted, we will have five public meetings. And as I noted in one of my first presentations, those dates have been set. So, if you didn't see those dates in the earlier presentation, we are very excited this time to announce those dates at the start of the process. We've never done that before, and we do hope that it helps you to follow along in the process and helps with your planning.

Two of those meetings will have the opportunity for oral comments to the Committee, and that will be the second meeting in July and the fourth meeting in January. Registration, as I noted, for those meetings will be made closer to the actual meeting dates. And you can stay up-to-date on these different things at

dietaryguidelines. And we'll be making announcements through our listserv.

Also noted, in addition to the public meetings and the opportunities for oral public comments, you will also have the opportunity to provide the Committee with written public comments. And those are welcome throughout the Committee's work, as Mr. Lipps noted in the beginning.

The public comment period for this Committee opened on March 12th. We have about 49 comments up until this date. That comment period is continuous. So, it will stay open until the Committee ends its deliberations in 2020.

I do want to note to the Committee and to the public that federal staff will support the Committee. They will group those comments by topic area. So taking the topic areas and your subcommittee structure, they will group them and they will do brief summaries around the comments with the comment numbers, just to help in seeing them as a collection. But the original comments

are available for the Committee and for the public review at regulations.gov.

Also during the Advisory Committee's work, you can follow their work at dietaryguidelines.gov. There you can register for meetings; as I've noted, see materials from past meetings, including the archived webcasts, meeting minutes, slides and handouts. Just give us a little bit of time to get those things posted. Again, a link to regulations.gov to submit public comments.

And as Drs. Obbagy and Pannucci both alluded to, you can review the progress on the topics and scientific questions and read monthly subcommittee updates. So, this is also a new element that we've added. Once a month, we'll do a bit of an update to the website, so that the public can follow along in the process.

We'll update the protocols as they become available. As I think Dr. Klurfeld noted, there are a number of different questions. All of those questions already are on our website. I

mean, I'll show a screenshot of that here in a second. But, once a month, we'll collectively do an update with the protocols and a brief subcommittee update, so you can get a sense for what's happening in between the public meetings. And also, you can get answers to any of your questions, and I'll talk a little bit more about that here in a second.

As Mr. Lipps noted, we have recently redesigned our website. That was led by colleagues here, Liz Rahavi and Stephanie Fu. We've always had a website. I think, historically, we have communicated more to somebody who follows the process, who is a health professional, a nutrition professional, who kind of is following this as a part of -- I mean, they have familiarity with it.

And now, we've grown to where we have new audiences and new people engaged in the process. That's partly in addition to the pregnancy and birth to 24 months work, because people who haven't a part of the Dietary

Guidelines, we're communicating to them as well. So, we took the approach of kind of communicating to newer audiences who weren't as familiar with what the Guidelines are and the process are for developing them.

So, for those materials around public meetings and public comments, you click on "Get Involved," the top right hand portion of the website. And from there, you can submit public comments and you can also register to attend meetings and see information from previous meetings.

The "Work Under Way" section is going to be a very important part of the website during the Committee's review of the evidence. This is where we will post the protocols and all the subcommittee updates and keep you posted on what's happening in relation to the work of the Committee.

So, the "Work Under Way" tab will be key. If you click on "Work Under Way" and look at the review of the science, you can see there's

information about the Advisory Committee. There will be information about the approaches for examining the evidence. This is where you can get to the list of topics and questions that have been shown by both Dr. Obbagy and Dr. TusaRebecca Pannucci.

So, if you scroll down, literally, every single question is there and you will be able to follow it. There's little icons that say, "This question is still to come." Reality is there are a number of questions and they can't all be done at once. And so, there will be a period -- you know, this one is still -- we haven't started working on it yet. This one is in the process of developing the plan for looking at it, or you're implementing the plan, or you have a draft conclusion. So, the website will be updated along those different steps, and you can follow the process with the little icons to the left.

The next section, just to note, is the "Most Popular Questions" section. We get a lot

of questions about the Dietary Guidelines, and you may have questions about the Dietary Guidelines. And we have a section about those questions.

And so, we do update this section regularly. So, if we're hearing a lot of questions, we're getting asked questions, or we see that there's questions circulating, we will update this to kind of try to address those.

So, it is divided into different topic areas. If you have a question, go here first and see if it is addressed. If not, you can always reach out to us. We have a "Contact Us," and our email address is there as well.

As we noted, this Committee's work will conclude with a scientific report for the Secretaries of Agriculture and Health and Human Services to consider as the Departments develop the 2020-2025 Dietary Guidelines for Americans. Once we receive that report, USDA and HHS will post the report at dietaryguidelines.gov for public comment. And we will also host a meeting

for the public to provide oral comments to the Departments on the Committee's report as well.

So, we encourage you to follow the process and get involved. We will make announcements at dietaryguidelines.gov. There is the formal process of announcements through The Federal Register notice process, and we will use that.

We will also use our listserv a lot. And if you don't know, you think maybe I'm on it, well, if you -- I think the last couple of weeks we did a call, sent out a listserv message around the opening the registration process, another email when the registration process was about to close, another email with the agenda for the public meeting.

So, if you didn't receive those emails, please sign up for our listserv. And you can do that by going to dietaryguidelines.gov, scrolling all the way to the bottom of that page. And you can click where it's circled there. It says, "Sign up to receive regular updates." And

we encourage you to do that.

I was just going to say, so if there's other discussion items, you are welcome to have it and we definitely have the time.

CHAIR SCHNEEMAN: Yes, we definitely have time. So, I thought what we could do at this point -- many of our Committee members haven't had a chance to say something. And so, we've heard a lot of presentations that help us understand the process and what we will be going through. So, I'd like to just go through and ask each Committee member, do you have something where you want additional information, something that you've felt is particularly important, or want some more clarification, because we have the whole group of experts still here? So, if you don't mind, I'm just going to ask each person if they have something they would like to put on the table.

So, Steve, I'll start with you.

MEMBER HEYMSFIELD: Okay. I had to step out for a minute, but I'm interested in the

question about the validity of self-reported food intake data.

DR. STOODY: So, for this, maybe Drs. Pannucci and Obbagy, do you all want to come up as well?

CHAIR SCHNEEMAN: What we can maybe do is go and collect several of these and then --

DR. STOODY: Sure. Handle them collectively?

CHAIR SCHNEEMAN: Yes.

DR. STOODY: Sure.

MEMBER HEYMSFIELD: The context is earlier in my career I did a number of studies looking at self-reported versus actual intake using doubly labeled water for measuring energy intake. There's pretty clear biases in that kind of data. And so, throughout my career, I've watched sort of the publications on self-reported intake and wondering about how accurate and representative they really are.

DR. PANNUCCI: Thank you for asking.

CHAIR SCHNEEMAN: I think what we'll

do, we'll collect several, and we'll keep track. And then, that way, you don't have to instantly think of the response.

MEMBER MAYER-DAVIS: So, this is actually a much less important question than his, and I appreciate his question because I think that's something we need to give a lot of thought to.

But I did notice, as I was reading through the various questions for the various subcommittees, that in quite a number of cases there's a good bit of overlap. And so, I'm just wondering how that's handled pragmatically, so that everyone can work as efficient, not creating duplicate effort. How is that generally handled?

CHAIR SCHNEEMAN: So, we'll take one more, and then, we'll let you respond to these, please.

MEMBER ARD: Maybe if they get too close.

So, I don't think I really have anything. I do think I will sort of put a pin, a

bookmark, so to speak, on the sort of question around the National Academy recommendation around the translation of the Committee report into the policy document, and wanting to stay abreast of what that deliberation looks like, so we can understand, is the Committee -- will there be adjudication of, yes, this isn't going to make it into the policy document and why?

DR. PANNUCCI: All right. I'll start by addressing Dr. Heymsfield's question about, essentially, the value of self-report dietary data compared to biomarker data, such as doubly labeled water. And doubly labeled water, of course, is an objective biomarker for dietary intake, or for energy intake rather. I should correct myself there. And that is a value for energy.

But, as I mentioned in my presentation, of course, you're tasked with providing food-based dietary guidance. And so, the dietary data from What We Eat in America are quite valuable in understanding the types of

foods and quantities consumed by Americans.

The error in self-report dietary data are recognized. There are different levels of error that can occur, either in reporting, in the databases, the estimates of the nutrients, et cetera. We account for some of that in the analysis that is done. So, even some of our colleagues work on some of the robust statistical methods that accommodate for some of the error in self-report dietary data. So, we don't brush that under the rug or ignore it by any means. But, for food-based dietary guidance, of course, food-based dietary recall is of utmost importance.

And I'll also speak to the 24-hour recall, the AMPM, also being a way to help people recall what they've eaten in great detail to the best that they can.

Does that help?

MEMBER HEYMSFIELD: Yes.

DR. PANNUCCI: Yes? So, it is quite valuable data, despite some of the error that

does exist and we acknowledge.

DR. OBBAGY: And I will just add, from a systematic review perspective, certainly most of the studies that we will be including in the reviews often do include self-reported dietary intake. And we have a part of our protocol process where we'll have thorough discussions about the methodology used around diet assessment for particular interventions and exposures that you'll be looking at. And then, as we work through the process and assess risk of bias of the studies, we'll certainly be taking those discussions in mind when we're assessing the sort of overall risk of bias of studies, especially around bias due to measurement of an exposure in observational studies, in particular.

So, there definitely is overlap. I believe the way that the subcommittee membership will be designed is, though, that there are members strategically placed, so that they're addressing topics where there are overlap. Certainly, our team is prepared to handle that

overlap. We don't want two subcommittees doing the same sorts of review of evidence. So, we will be sure to make sure that, where there is that overlap, we'll be prepared to kind of figure out where it is going to be addressed and where you don't want to duplicate efforts.

DR. PANNUCCI: Similarly, the data analysis and food pattern modeling is a cross-cutting subcommittee that will be having conversations across the committees as we develop protocols and do the analyses to have conversations.

DR. STOODY: And to Dr. Ard's comment, definitely noted. To be totally honest, we've been in the phase of getting this Committee in place and getting into the stuff. I think we can definitely plan to have more conversations and give more information about that next step as we move forward in subsequent public meetings.

MEMBER BAILEY: Regan Bailey.

I have a two-pronged question. The first, there are 62 questions. Are there any

questions that you're immediately concerned that there are not enough data available to answer?

And my second question is, while we do have NHANES data across all ages, there's very limited sample size for infants and pregnant women. So, Dr. Dewey mentioned that. There's about 1200 women from 1999 through 2014. So, even combining all of those surveys, and that's to say nothing of lactating women. There's a couple hundred lactating women in all of those survey years.

So, I am just wondering what your concerns are at this point about the lack of data from NHANES across a broad representation of population groups at risk and the availability of data for some of the questions that we have.

MEMBER BOUSHEY: This is Carol Boushey.

And I kind of in a way have a question very similar to yours, Regan, because what I was thinking was, I looked at some of them, and do we have to actually do a review to ensure inadequate

or limited data? And so, that was the other. I mean, do we have to do a review to do that or can we do it by group consensus for some of the questions that were in there?

MEMBER STANG: Jamie Stang.

And I guess my question is, it follows a little bit on some of the other questions, but also what we know about the adequacy of the databases, particularly when it comes to infants and children under the age of two, particularly when you get into things like some of the traditional feeding patterns and the cultural and ethnic-specific feeding patterns.

DR. OBBAGY: I can speak to the question about how to handle what we might consider an empty review or one where there's just not very much evidence. I do think it's really important to go through the process of doing the literature search and identifying what is out there. If there's nothing out there, then it's a very easy conclusion and grade. And so, I do think it's really important to document where

we don't have that evidence, and then, draft up some research recommendations to that point, because it is an important resource for funding agencies and researchers. And I think it's an important topic of public health concern, and I think it's a good way to flag those areas where there's a lack of research. So, we will go through that process. But, if there's no studies, we can really simplify the process of answering the question.

(Laughter.)

DR. PANNUCCI: Similarly, with the data available, I think that where there are limited data, we can look forward to research recommendations and things like Kellie is very well versed in leading efforts around the B-24 data. It's a collaborative, yes, collaborative? Yes, B-24 data, collaborative -- what? Federal Data Consortium. B-24, Federal Data Consortium, looking forward to data that could be acquired in the future.

MEMBER LEIDY: Hi. This is Heather

Leidy. A couple of questions.

The first one is really about the inclusion/exclusion criteria with NESR or some others. And that is, is obesity considered a disease condition and, if so, if it's part of the exclusion criteria, are the majority of those studies excluded? Along those lines, if they are healthy, yet obese individuals that are healthy, are those, then, in a different category because they're not expressing disease? So, in essence, it's more about prevention, not treatment. So, that's my first one, sub-question.

Along those lines, there wasn't mention of crossover designs. I'm assuming they're probably in the category of a randomized controlled trial, but some crossovers don't actually serve as their own control. So, where do they fit? I didn't see them in the exclusion criteria.

And then, the last question with that along those lines, does the Committee or the subcommittees have the ability to bring up

studies or data, publications, that are not included in these types of reviews? So, for example, the meta-analyses or non-federal survey data. This was kind of mentioned earlier, but I guess my question along those lines, are we permitted to bring those types of studies up for discussion in the subcommittees or are we only restricted to the data that gets reviewed from your perspective?

MEMBER DAVIS: This is Teresa Davis from Baylor College of Medicine.

So, there were systematic reviews that were conducted in the 2015 Dietary Guidelines, and then, for the birth to 24 months working group. So, are some of these systematic reviews that are being proposed, are they updates to those that were previously done or all they all new ones that are being proposed?

DR. OBBAGY: So, I will start with the last question there about some of the existing reviews. I think that's a question that we'll work with you all on. The existing reviews, for

example, from pregnancy and birth to 24 months, the literature searches for those are much more recent, although there is still a gap from the time where we finish that until the present time. So, I think we'll certainly want to have discussions with you all from your perspective as to whether an update is warranted for the most recent reviews.

I do think that, for 2015, those will need to be updated to reflect the last five or so years of data. And so, I think that there could be some variability, but I think it's part of your discussion as a Committee to determine how timely and whether that update is warranted ultimately.

To your question about the obesity, that is an excellent question. I mean, I think that really the intent is for, say you have a study that includes only obese individuals, and it's really a study designed to sort of treat that obesity and reduce weight. Then, we might not include that study.

However, if we're looking at some other outcome, say cardiovascular risk factors or type 2 diabetes or prediabetes, if there's a population with obesity, we're not going to exclude a study just because they're obese individuals. We would really only exclude those in which the outcome of interest in the review was obesity, risk of obesity.

That's not making --

MEMBER LEIDY: If you caught these individuals, well, then, we will see outcome is still --

DR. OBBAGY: Yes. So, we would not exclude it. We would not probably consider obesity a disease that we would exclude that study on the basis of that. We would probably put that more in that category of at risk for chronic disease. And we do include studies where individuals are more at risk. But it sort of depends on what the outcome of the systematic review is as to what outcomes, how we would handle some of those situations. So, that's not

a great answer, but I do think it's a question specific and what the outcome really is that you're looking at.

MEMBER LEIDY: So, then, we also have crossover designs.

DR. OBBAGY: Oh, yes, crossover designs. So, crossover design studies are included as part of the randomized controlled trial category. And, in fact, the Risk-of-Bias 2.0 tool has a special subset of questions that are geared specifically towards crossover design studies. So, when we do come across those, we have a tool that addresses issues specific to those studies.

CHAIR SCHNEEMAN: And I think Heather also asked a question about, in the subcommittee, bringing in studies that were not necessarily included in the review.

DR. STOODY: So, Julie can speak to original studies. But kind of thinking about the meta-analysis question or other data sources, the systematic reviews themselves, we ask you to base

conclusions based on the body of included studies in that NESR review. There can be the opportunity, though -- I mean, you're ultimately developing a report with recommendations. And so, I think there can be the opportunity to look at existing meta-analysis or a Cochrane review, or something, to add some contextual information. But the conclusions themselves should be based on the original, you know, the systematic review, NESR systematic review work. But it's like any publication, I mean, you can speak to what other evidence is out there in your discussion and the report.

CHAIR SCHNEEMAN: We'll gather some more questions.

MEMBER SABATE: Okay. Joan Sabate.

The Dietary Guidelines, when they started in the '80s, were basically nutrient-based. Then, slowly evolved throughout the years to be food- or food-group-based. And in 2015, they were food-pattern-based, recommending three health patterns as the prototypes. I mean, one

being the vegetarian, the one being the Mediterranean, and the other, I think it was called the healthy American diet, or something like this.

So now, in the 2020 we have close to 60 questions that we have to address. My question is, what's the task of this Committee? If we take these three dietary patterns, I mean, are those still relevant or those obsolete? Because if they are relevant, then we have to multiply the 60 times 3. So, it's 180 questions that we have to address.

(Laughter.)

So, I'm not trying to be malicious, but I'm trying to say, are we going to be able to address or that's our task, to know if, for instance, in babies or in toddlers or in adolescents, I mean, the three dietary patterns can accomplish the goals that you want, or what? I'm saying that's my question. I mean, is it 60 or 180 questions that we have to address?

DR. PANNUCCI: We'll wait for our

three.

MEMBER SNETSELAAR: Okay. My question relates to what will happen eventually with what we're doing relative to our recommendations. Will you get advice from the public, for example, on how our recommendations might best be presented to them, so that they're most usable for them? Because our ultimate goal is to see the American public change, and I just wondered if you had some thoughts about that or some ideas.

MEMBER VAN HORN: Relative to what was just asked, I think, again, the fact that we're now introducing the younger generation and getting at those kinds of questions, the ability to collect data, even on breastfeeding behavior, you know, and the fact that that's a whole topic area in and of itself that is evolving continually, and the importance of it related to the new findings related to epigenetics and other things that are very much influenced by initial feeding and duration of that feeding, et cetera.

I just would hope that we do the best we possibly can, knowing how difficult it is to assess those kinds of questions. But, again, the opportunity is so unique and available to us this time, that we should try to do everything possible to capture those kinds of questions.

DR. PANNUCCI: Well, I can start to address Dr. Sabate. I think that the task to look at the food patterns is, thankfully, within those 63 questions, not multiplying. Those are the three patterns that were developed for 2015-2020, but it might be that the evidence suggests other patterns for 2020-2025.

So, one of the questions -- I only can remember the gist of it -- was to examine whether the evidence will drive differences to the food patterns through food pattern modeling. So, that's something that will be a conversation of part of the Data Analysis Food Pattern Modeling Subcommittee, and we'll look forward to more conversations.

But I think that is within the 63

questions, not a multiple of them.

DR. OBBAGY: And from the systematic review perspective, our reviews looking at dietary patterns and health, we'll look at any research that's examined any sort of dietary pattern in relation to health. So, we're not going to be looking just for studies that examine the three patterns we already have in relation to health. So, we're taking sort of a broad look at any patterns, and then, the results of those reviews are what will inform TusaRebecca's work, and then, your work at determining what patterns you might recommend for the next iteration of the Guidelines.

DR. STOODY: And then, Dr. Snetselaar, to your point, I think what you're asking about is really the implementation piece, which is really the million dollar question. You know, we can develop guidance, but how to get it to people and how those people actually implement that guidance.

I think that is, it's a separate --

it's a next step. I think if we can focus on the review of science and talk about what those recommendations should be, there should definitely -- I mean, some of our federal partners do work in this space of the how. How do we get people to change? But, if we can focus on "what" piece, I think that's the core ask for this Committee.

CHAIR SCHNEEMAN: I was going to say, you raise various points that should be a part of, worked into our thinking all the way through.

MEMBER NOVOTNY: Rachel Novotny.

I have really kind of three areas I'm mulling that have pretty much already been discussed, but my take on them is -- one is, the first one is around the scope really of the Guidelines or the guidance that we want to come up with, and specifically, with regard to subpopulations or special populations. I'm of the opinion that it would be important to address some of those, considering the use to which the Guidelines are intended, thinking about food

assistance and some of those other intended uses, along cultural lines or ways that if we can do it according to ethnic groups and NHANES.

But, in a similar vein, wondering if, when, and how some other datasets could be drawn in for some of those very purposes. And I realize we've got a lot on our plate already. So, those are the things I was kind of mulling.

And then, a more granular thought of wondering if you've given thought yet to quantifying breastfeeding for the birth to 24-month group. I realize it's not just about quantifying it, but for that part of it, for looking at intake.

MEMBER MATTES: Rick Mattes.

It's easy to get punchy thinking of the power that we have at our disposal here.

(Laughter.)

Can you help me define a barrier? Say we're interested in eating patterns, and to determine their veracity, we want to understand some mechanistic information about them. Are you

capable of doing systematic reviews on things like brain reward mechanisms and eating patterns or gut-brain access in feeding patterns? I mean, it's one thing to look at the pattern, but to know if it's real, sometimes you want to know the mechanism behind it. Is that part of our purview? Are you capable of doing that?

MEMBER BAZZANO: Okay. This is Lydia Bazzano.

I have two questions. One of them is sort of more of an operational thing. Given that the systematic reviews are only longitudinal data in some way collected, and not cross-sectional, on all but the food pattern modeling and the data analysis parts; those are cross-sectional using NHANES or other databases. I just want to know how it all fits together. I think there was some talk about how that works together and what exactly we're doing.

And then, some of the questions -- my second question related to, I guess it gets at the same special populations issue. Some of the

interesting questions in dietary patterns were about neurocognitive outcomes in sarcopenia. And we do talk about the life course, but we are lumping everybody over 18 together, aren't we, except pregnancy and birth to 24 months right now?

MEMBER DEWEY: I have just one very practical question. And that is, whether it would be possible to map the existing systematic reviews against the 60-some questions we have, so we know what's out there and what we're starting from.

Thank you.

DR. STOODY: I can just say, generally, about your question -- and I think there are a couple of questions that got at subgroups, whether it be -- whatever the subgroups are. I think as much as you can speak to that based on the evidence base, that is wonderful. In the systematic review work, and Julie talked about the grids that they develop, the data extraction that they do. They regularly

pull out information about subgroups as much as possible. And I think if you can make conclusions based on subgroups, that is very useful. I think it's really based on what evidence is available. So, you can only do that as much as the evidence allows you to do it. So, it is something that's built into the process.

And I think, similarly with the data analysis, as much as you can speak to subgroups, that will be done, including age, you know, different age groups. In the age groups, there's some flexibility there. I mean, again, it's based somewhat on age groups, somewhat on the data that's available, but it's not set in stone specific cut-points on age this to this. That's up for the Committee to discuss as well.

With regard to bringing it all together, I mean, that is a very important part of the final phase of this process. So, throughout the course of this work you'll do systematic reviews. I'm sorry. Throughout the course of this work you'll do systematic reviews.

You'll do data analysis. There's food pattern modeling.

I know that it is a tight timeline, but at the end of it, bringing it all together is really like the most important, I mean an extremely important part of it. So, bringing it all together in your report. In the past, there's been some front chapters that kind of bring it all together and speak to it collectively.

But what you'll find is that, I mean, the systematic reviews inform the food pattern modeling. I mean, it works out you get different perspectives of it, looking at what current intakes are related to what you see in the systematic reviews, related to what ultimately is recommended. I mean, it does talk to each other. It's just it's a little bit later in the process, once you've kind of gotten some conclusion statements. It's putting those pieces together.

So, really, collectively, it covers nutrition science in a number of different ways,

which we found to be very useful, the systematic review pace, and then, also, thinking about modeling to meet -- you know, what you see in the systematic reviews, how does that result in developing patterns, and how does that relate to -- does that allow people to meet nutrient needs?

I mean, it is a story. So, I think to kind of speak to that complementary aspect, we just need to be a little bit further down the road, so you can have some conclusions. And because there is so much crossover, that will be really important, too. Like Julie said, you don't want to duplicate efforts in the systematic reviews, but all these topics are interrelated. And so, having that package of conclusions and bringing it together to kind of make final recommendations/advice to the Departments really is a conversation across all of the subcommittees, across all of the questions. So, I think that's just a little bit further down the road to see how it all comes together.

CHAIR SCHNEEMAN: So, was one of you

going to comment on Dr. Mattes' question?

DR. OBBAGY: Yes. You know, I think that's an important question. To me, those are different questions, the ones that you have on your list already. And while we're capable of answering a question like that, to me it is a separate and different question than the ones that you have currently on the table. And so, given that your charge is really to answer those questions, I'm not sure that that's possible for this go-round. But I appreciate that understanding the mechanisms underlying some of these relationships is, of course, important. Just limits on time and resources.

And then, to your question about mapping of the systematic reviews that are existing, we can definitely do that. And I think that will be a really important first step. As we start to work within the subcommittees, we can certainly bring that information to you all.

I think there's probably somewhere in the order of 20-ish reviews that may be relevant

to your questions, but I think that that's certainly something that we would bring to you for review, to confirm that you would agree with that assessment.

DR. PANNUCCI: And then, to add to that, we've anticipated some of the analysis that might be needed to answer some of the questions for data analysis, so we can map those to the questions and the data that are available to answer questions. So, we've already started that mapping process for you. We'll help you with understanding what data is available, what analysis has been completed, what's in the works, and where conversations will be needed on how that data might be useful in your deliberations.

And then, I believe there was a question about quantifying breastfeeding from Rachel. And that's a conversation that is ongoing. I think that that's something that we need to talk about more, around the limitations and the challenges around quantifying breastfeeding and how we're going to integrate

that into your discussion.

DR. OBBAGY: But, at least from the systematic review perspective, the intervention or exposure of human milk feeding will certainly capture any sort of type of breastfeeding, whether it's frequency, amount. So, that sort of quantification of breastfeeding will also get captured in the systematic reviews to the extent that the data breaks it down and reports it that way.

VICE CHAIR KLEINMAN: Just about all my questions have been asked. I do think that the question asked about mechanisms is quite relevant. As we're making these recommendations around dietary patterns and food consumption and outcomes, it's always nice to know that there's a biologic basis for these recommendations. And so, to the degree that we can have some of that to add context to these recommendations, I think that would be very relevant and persuasive to the population as we put these recommendations forward. So, that's just a comment.

The outcomes that we are charged to look at are often reported both qualitatively in some cases and quantitatively in other cases. And I'm wondering if in the process of the systematic reviews we could have some indication of that, since we have to judge the level of evidence. I think it would be very helpful for us to be making that judgment knowing what kind of data we're dealing with.

DR. OBBAGY: Yes, and very similar to what I talked about with measurement of dietary intake, we'll also upfront have a very thorough discussion about measurement of the outcomes. And then, that will feed, then, into risk-of-bias assessments and your sort of synthesis and grading of the evidence. So, certainly, having an upfront discussion about what are the strongest, most valid, and reliable measures for assessing an outcome and making sure that that is weighed and considered throughout the process.

CHAIR SCHNEEMAN: Just to add to that, I assume that biomarkers become one of the issues

there and whether something is a valid biomarker or not for the outcome.

These are great comments and questions you have all had. So, I'm glad we had the time to include that in our discussion. I think it's been certainly very helpful to me. And I'm not sure you expected to suddenly be a panel over there, but we really appreciate the thoughtful responses to the issues and the questions that the Committee is raising.

So, Eve, I'll turn it back to you to close this out and set us up for tomorrow, right?

DR. STOODY: Excellent. Thank you.

So, we'll end a little early today. We will reconvene tomorrow here at the same place at 8:30, and we look forward to seeing you then.

Thank you.

(Applause.)

(Whereupon, the above-entitled matter went off the record at 3:35 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: 2020 Dietary Guidelines
Advisory Committee Meeting

Before: USDA

Date: 03-28-19

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter