

UNITED STATES OF AMERICA

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DEPARTMENT OF AGRICULTURE
AND
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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DIETARY GUIDELINES ADVISORY COMMITTEE

+ + + + +

FIFTH MEETING

+ + + + +

TUESDAY, APRIL 13, 2010

The meeting came to order at 9:00 a.m. via webcast, Dr. Linda Van Horn, Chair, presiding.

MEMBERS PRESENT:

- LINDA VAN HORN, PhD, RD, LD, CHAIR
- NAOMI K. FUKAGAWA, MD, PhD, VICE CHAIR
- CHERYL ACHTERBERG, PhD
- LAWRENCE J. APPEL, MD, MPH
- ROGER A. CLEMENS, DrPH
- MIRIAM E. NELSON, PhD
- SHARON M. NICKOLS-RICHARDSON, PhD, RD
- THOMAS A. PEARSON, MD, PhD, MPH
- RAFAEL PEREZ-ESCAMILLA, PhD
- XAVIER PI-SUNYER, MD, MPH
- ERIC B. RIMM, ScD
- JOANNE L. SLAVIN, PhD, RD
- CHRISTINE L. WILLIAMS, MD, MPH

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ALSO PRESENT:

SHANTHY BOWMAN, PhD, ARS, USDA

CAROLE DAVIS, MS, RD, CNPP, USDA

KATHRYN McMURRY, MS, ODPHP, HHS

HOLLY McPEAK, MS, ODPHP, HHS

RADM PENELOPE SLADE-SAWYER, PT, MSW, ODPHP,
HHS

ROBERT POST, PhD, CNPP, USDA

WENDY BRAUND, MD, MPH, MEd, ODPHP, HHS

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C-O-N-T-E-N-T-S

<u>AGENDA ITEM</u>	<u>PAGE</u>
Opening Remarks	4
Subcommittee Topic Area Discussions:	
Carbohydrates and Protein.....	22
Fatty Acids and Cholesterol Subcommittee .	153
Energy Balance Subcommittee.....	239
Adjourn	

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

9:00 a.m.

DR. POST: Ladies and gentlemen, good morning from Alexandria, Virginia. Thank you for standing by. Raj Anand, the executive director of the Center for Nutrition Policy Promotion of the United States Department of Agriculture is on the agenda. Unfortunately, he is unable to be here.

My name is Robert Post, and I'm the deputy director for the Center. I will be representing USDA and officiating on his behalf.

Welcome to this webinar of the 5th meeting of the 2010 Dietary Guideline Advisory Committee. I'd like to begin by thanking the Committee members for their continuing support and invaluable contributions in developing the 2010 Dietary Guidelines for Americans.

As we move closer to the end of this process, I can't express my gratitude enough to the members for their dedicated

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1 service in evaluating the science for the
2 development of the ever-so-important Dietary
3 Guidelines recommendations. Their work has
4 never been more critical as USDA and its
5 collaborator, the Department of Health and
6 Human Services, work toward reducing the
7 public health problems of obesity in
8 preventing diet-related diseases.

9 I'd also like to recognize the
10 continued cooperation between CNPP and the
11 Agricultural Research Service at USDA, as well
12 as our wonderful partners and collaborators,
13 the Department of Health and Human Services,
14 in seeing the 2010 Dietary Guidelines process
15 further. Today, all of the Committee members
16 are participating in two-way webinar from
17 their home site. At our onsite locations in
18 Virginia are Ms. Carole Davis, the director of
19 the Nutrition Guidance and Analysis Division
20 of CNPP. Carole is the designated federal
21 officer and co-executive secretary for the
22 DGAC.

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1 Rear Admiral Penelope Slade-
2 Sawyer, director of the Office of Disease
3 Prevention and Health Promotion at HHS.

4 Dr. Wendy Braund, acting deputy
5 director, Office of Disease Prevention and
6 Health Promotion, and Ms. Kathryn McMurry,
7 senior nutrition adviser at the Office of
8 Disease Prevention and Health Promotion of
9 HHS, and a co-executive secretary for the
10 DGAC.

11 The Dietary Guidelines Advisory
12 Committee has a very important charge which
13 includes informing the Secretaries of both
14 departments of changes to the Dietary
15 Guidelines that are warranted based on a
16 preponderance of the most current scientific
17 and medical knowledge. Placing their primary
18 focus on the review of scientific evidence
19 published since the last DGAC deliberation
20 placing their primary emphasis on the
21 development of food-based recommendations.
22 And preparing and submitting an advisory

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1 report of technical recommendations with
2 rationales to the Secretaries of USDA and HHS.

3 The charters also state that DGAC
4 responsibilities did not include translating
5 recommendations into policy or communications
6 documents.

7 I'd like to explain the purview
8 under which the Committee operates. This
9 Committee is governed by the Federal Advisory
10 Committee Act, or FACA. FACA was established
11 to assure that advisory committees provide
12 advice that is relevant, objective and open to
13 the public, act promptly to complete their
14 work, and comply with reasonable cost controls
15 and recordkeeping requirements.

16 Therefore each public meeting has
17 been and will continue to be announced in the
18 Federal Register through a public notice. As
19 part of the open transparent process the
20 meetings of the full Committee are open for
21 observation by the public, and any
22 deliberations that occur between meetings such

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1 as those in topic-specific subcommittees, are
2 brought back to the full Committee at a public
3 meeting - as you will hear today and tomorrow.

4 During the meeting all public
5 participants will be in a listen-only mode.
6 The public has opportunities to participate in
7 the process by providing written comments to
8 the Committee through our online public
9 comment database, www.dietaryguidelines.gov.

10 In addition to the rules of FACA,
11 I'd like to also remind the Committee of some
12 rules of engagement. The Dietary Guidelines
13 Advisory Committee members should continue to
14 refer any individuals to the dietary
15 guidelines management team to contact them
16 personally so that they get information about
17 their work to the Committee. To support the
18 requirement that the Committee's work be
19 transparent to the public, Committee members
20 are not able to speak or give presentations to
21 any individual or outside group regarding the
22 work of the Committee as this would be

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1 inconsistent with the advisory committee
2 operations.

3 Let me now turn the microphone
4 over to Penny Slade-Sawyer from HHS who would
5 like to say a few words.

6 REAR ADMIRAL SLADE-SAWYER: Good
7 morning. I am Penny Slade-Sawyer, deputy
8 assistant secretary for disease prevention and
9 health promotion from the Department of Health
10 and Human Services. And on behalf of HHS I'd
11 like to join Dr. Post in welcoming members of
12 the Dietary Guidelines Advisory Committee, as
13 well as the listening members of the public.
14 As the Committee enters the home stretch I'd
15 like to convey the deep appreciation of the
16 Department of Health and Human Services for
17 your many hours of service to ensure that the
18 Dietary Guidelines for Americans continue to
19 reflect the preponderance of current
20 scientific and medical evidence relating
21 nutrition and health.

22 Your expertise is invaluable, and

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1 your commitment to public service is noble.
2 The Department of Health and Human Service
3 leaders are looking forward to receiving your
4 completed report in the coming months, in
5 order to begin development of the official
6 federal policy along with the Department of
7 Agriculture staff. Perhaps the excitement at
8 the Department is overshadowed only by the
9 excitement of the staff members in this room
10 who have provided technical and organizational
11 support to your Committee throughout this
12 process. We are grateful for all that has
13 gone on and continues to move forward as this
14 report is developed.

15 Best wishes for a productive and
16 enjoyable meeting. Thank you.

17 DR. POST: Well, thank you,
18 Penny. And speaking about transparency
19 earlier, we are very excited to be
20 broadcasting this meeting live via the
21 worldwide web, again, like we did at the last
22 two meetings. And having the Committee

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1 participate from their home locations is
2 exciting as well. Using this technology
3 enables us to reach a more varied and larger
4 audience of interested parties, and have the
5 added benefit of providing for a recording of
6 the meeting that can be used for future
7 reference. These recordings are easily
8 accessed at an archive at
9 www.dietaryguidelines.gov.

10 These individuals who have
11 registered for this meeting from across the
12 nation as well as internationally are
13 participating today and tomorrow. We were
14 quite impressed at the last meeting that we
15 had registered attendees from around the
16 world. At this meeting, now that we have
17 about 500 registrants for each day, from the
18 national side, but we have also doubled the
19 global reach with attendees viewing the
20 participation from Mexico, Brazil, China,
21 Canada, Uruguay, Lebanon and Peru just to name
22 a few.

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1 I'd like to review a few technical
2 points for public participants who are viewing
3 today. On your screen you see some relevant
4 information. If you experience technical
5 difficulties you may contact WebEx technical
6 support, toll free, at 1-866-239-3239. This
7 information was also emailed to you at the
8 time you registered for the meeting. A
9 separate technical assistance number for our
10 international participants was also provided,
11 and also can be seen on your screen.

12 The staff here in the room with us
13 will be monitoring an email line, so to speak,
14 where the public participants can send notes
15 of any technical difficulties while the
16 meeting proceeds.

17 As you see on the screen, the
18 email address is tech_issue@yahoo.com. Please
19 note that the staff will not respond to
20 emails. It is simply one of the several ways
21 that we are monitoring the streaming
22 efficiency of the meeting for the public. We

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1 value your feedback on these webinar meetings,
2 and after the meeting you will receive a
3 survey from WebEx in order to measure your
4 satisfaction with attending this online
5 meeting.

6 As in the past a transcript and a
7 written summary of this event will be posted
8 to our website as they become available. The
9 transcript and the minutes from the fourth
10 meeting held in November, 2009, are available
11 at www.dietaryguidelines.gov.

12 Because this meeting is being
13 streamed live to the public, I'd like to ask
14 that Committee members clearly state their
15 names before speaking. This is particularly
16 important in facilitating clear deliberations
17 for the public for following this proceeding.

18 And with that I'd like to turn the meeting
19 over to the chair of the Dietary Guidelines
20 Advisory Committee, Dr. Linda Van Horn.

21 Linda.

22 DR. VAN HORN: Thank you, and

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1 good morning to Committee members and DGAC
2 support staff, and welcome to our public
3 participants who are watching via the web
4 today. Although the Committee members are not
5 all in the same room today we are expecting to
6 have a very productive and successful meeting.

7 As the Committee has been
8 reviewing the state of nutritional science we
9 are all continually reminded of the relevance
10 of our work to public health in the United
11 States, especially as it relates to the
12 obesity epidemic we are facing. As we all
13 know the work undertaken by this Advisory
14 Committee is immense, but also provides us
15 with the opportunity to develop a strong,
16 concise advisory report of food-based
17 recommendations to inform the federal
18 government as they develop the 2010 Dietary
19 Guidelines for Americans policy.

20 Since the fourth meeting of the
21 DGAC in early November the Committee and our
22 support staff have been working very hard to

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1 complete proposed conclusion statements and
2 supporting summaries of the evidence of our
3 remaining research questions and have been
4 preparing drafts of the chapters of the
5 report. The focus of this meeting will be to
6 come to consensus on the science for these
7 questions and consider the integration of our
8 conclusions and food-based recommendations.

9 We will hold our sixth and final
10 public meeting next month where we will
11 present and come to consensus on our Advisory
12 Report as well as discuss any remaining
13 issues. As a reminder for the public, the
14 Committee has seven subcommittees, each with
15 its own topic listed on the agenda. In
16 addition to the seven subcommittees we also
17 have the science review subcommittee that
18 provides oversight and guidance related to the
19 technical review of the evidence.

20 We have also initiated formulating
21 a new chapter for the Report which will
22 address the total diet concept. Key numbers

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1 are the energy balance and weight management
2 carbohydrate, protein, nutrient adequacy and
3 sodium, potassium and water subcommittee will
4 be working together to prepare this chapter.

5 Other Committee members will be
6 actively involved in the writing of the
7 translational integration chapter of the
8 report. These will be further discussed at
9 the end of tomorrow's session.

10 Today and tomorrow we hope to
11 propose conclusions supported by the evidence
12 and have discussions on the research questions
13 that are presented.

14 Since time is limited and we have
15 a lot to accomplish over the next few days our
16 Committee members have agreed to keep their
17 presentations succinct. In addition to our
18 evidence reviews that will be summarized in
19 our report. The details of the evidence
20 reviewed will also be available in the
21 electronic database accessible by the public
22 called the USDA Nutrition Evidence Library, or

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1 NEL. As you may have heard it referred to in
2 past meetings, we will refer to it as NEL.

3 Having a Nutrition Evidence
4 Library ensures that the details of our
5 science review are well documented,
6 transparent and reproducible. Our systematic
7 process also reduces reviewer bias and better
8 standardizes the approaches used by the
9 various subcommittees. For questions using a
10 NEL systematic review, there are some general
11 criteria and information that apply broadly to
12 our work that I'd like to briefly review.

13 The first step of the evidence
14 review process was to generate research
15 questions that led to the search and sort plan
16 to search the scientific literature. In
17 general, literature in our review met the
18 following inclusion and exclusion criteria.
19 Inclusion criteria generally entail studies
20 with human subjects, English language, as well
21 as international. Sample sizes of the minimum
22 of 10 subjects per study arm, and a preference

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1 for larger sizes if available, dropout rates
2 less than 20 percent, with a preference for
3 smaller dropout rates, and populations of
4 healthy individuals and those with elevated
5 chronic disease risk.

6 Most questions only considered
7 healthy or risk populations, but other
8 populations were included when it was
9 pertinent to the question.

10 Exclusion criteria generally
11 entailed studies of medical treatment or
12 therapy, disease subjects such as people
13 already diagnosed with a disease related to
14 the study's purpose, hospitalized patients,
15 malnourished or Third World populations, or
16 disease incidences that are not relevant to
17 the U.S. population such as malaria, animal
18 studies, in vitro studies, and articles that
19 are not peer reviewed.

20 One main exception to this list
21 resulted after much discussion among the DGAC
22 members regarding the use of cross-sectional

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1 studies. The agreement was made to not use
2 cross-sectional studies except in cases where
3 only limited data were available. The
4 Committee favored the use of randomized
5 controlled trials and prospective cohorts.
6 Other exceptions to the list of inclusions and
7 exclusions as well as additional criteria
8 considered will be noted by each subcommittee
9 during their presentations. In some cases the
10 systematic review of the literature went back
11 to cover literature on infants whose potential
12 manifestation of disease in infancy can
13 continue on across the lifespan.

14 The Dietary Guidelines themselves
15 however provide recommendations for ages two
16 and above. Now the Committee is grading the
17 body of evidence supporting our conclusions
18 using an approach that the group had agreed
19 to. You can see the criteria here which
20 takes into account the quality of the studies,
21 the consistency of finding, number of studies
22 supporting the evidence, magnitude of the

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1 effect or outcome, and generalizability.

2 Based on these criteria the
3 conclusions statement will be given a grade of
4 I, strong, II, moderate, III, limited, IV,
5 expert opinion, or V, grade not assignable.
6 The grading chart you see on this slide
7 further describes each grade and can be found
8 on the Dietary Guidelines website under
9 meeting five. Most of our questions were
10 answered using the NEL systematic review
11 process. For some questions it was decided
12 that a formal NEL review was not needed. In
13 some cases, such as when only a brief update
14 was needed, other sources of evidence were
15 used when appropriate, such as the 2005
16 Dietary Guidelines Advisory Committee report,
17 IOM reports, and the Physical Activity
18 Advisory Committee report.

19 For other questions, food pattern
20 modeling was used to understand the
21 implications of specific recommendations on
22 the total diet. And for others data analyses

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1 were used to answer the question.

2 It is important to note that only
3 conclusion statements for which there was a
4 formal DGAC NEL review are graded. I'd also
5 like to mention that over 900 public comments
6 were received throughout the process thus far.

7 Each subcommittee has, and will continue, to
8 take these into consideration as they continue
9 their work.

10 Now that we have reviewed the
11 overall systematic approach being used, we are
12 ready to begin hearing some specific results.

13 Each subcommittee will present their research
14 questions, propose conclusion statements, and
15 then briefly describe the evidence supporting
16 those conclusions. The proposed conclusions
17 will be presented first, but I would like to
18 remind the public that the subcommittees began
19 with open-ended questions and conducted
20 extensive surveys of the scientific literature
21 and graded the evidence before drafting these
22 conclusions.

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1 When appropriate the
2 recommendations from other national
3 organizations will also be summarized. When
4 there are inadequate data the DGAC has drafted
5 research recommendations. I would also like
6 to remind everyone that everything being
7 presented today and tomorrow is in draft form.

8 As a Committee we need to come to agreement
9 on all conclusions if possible.

10 Lastly each Committee member
11 should please remember to announce themselves
12 when speaking to help the public follow along.

13 With that I would like to begin
14 with our first subcommittee which will be from
15 the Carbohydrates and Protein Subcommittee
16 chaired by Joanne Slavin.

17 Joanne.

18 SUBCOMMITTEE TOPIC AREA DISCUSSIONS:

19 CARBOHYDRATES AND PROTEIN

20 DR. SLAVIN: Nice to be here
21 today, and I think that I won't have control
22 of my slides, so I will just have to say next

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1 slide as we move on.

2 So I'd like to first thank my
3 Committee members that are listed on the first
4 slide, and also the staff that helped us with
5 the large number of questions.

6 So we are going to start with the
7 protein questions, and then we will go on to
8 the carbohydrate questions.

9 Two protein questions of the
10 relationship between the intake of animal
11 protein products and selected health outcomes,
12 and then the relationship between vegetable
13 protein and/or soy protein and selected health
14 outcomes.

15 And we have a long list of
16 carbohydrate questions that we will then go
17 through. The first: health benefits of
18 dietary fiber, whole grains and selected
19 health outcomes. In adults, the associations
20 between intake of sugar-sweetened beverages
21 and energy intake and body weight.

22 Number four, non-caloric

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1 sweeteners related to body weight.

2 Number five, the impact of liquid
3 versus solid foods on energy intake and body
4 weight.

5 Number six, the role of
6 carbohydrates, fiber, protein, fat and food
7 form on satiety.

8 And number seven, the role of
9 prebiotics and probiotics and health.

10 I do want to mention number three,
11 some of these overlaps with our Committee and
12 other Committee, the childhood sugar-sweetened
13 beverages was actually in the energy balance
14 Committee, and other of these questions for
15 our subcommittee have been presented before.
16 So these are the remaining questions that have
17 not been publicly presented before.

18 Next slide. Animal and vegetable
19 protein, the search strategy for these
20 questions was the same, so we are going to
21 talk first about the search strategy. These
22 were questions - protein was a new area for

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1 the Dietary Guidelines. It really wasn't a
2 separate question before, and because of the
3 importance of protein many public comments
4 about the importance of protein, we wanted to
5 include protein as a focus of this 2010 DGAC
6 review.

7 So we were starting from no data
8 for proteins, so the way we went after this
9 was a NEL evidence-based review. We made the
10 decision to go back to January of 2000 to
11 present to search, and for the cancer outcomes
12 we only looked at prospective cohort studies,
13 and I know Linda has mentioned that before
14 that as we went into this process we tried
15 very hard to go with the strongest studies we
16 could find. So we tended to stay away from
17 cross-sectional studies if we could find other
18 studies.

19 The cross-sectional studies did
20 come up at the beginning but they were later
21 excluded because we had other stronger study
22 designs. Original articles included in

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1 systematic reviews or meta-analyses were
2 excluded, and I really appreciate the staff
3 for helping us out on this, because we didn't
4 want to essentially double count studies that
5 had already been reviewed in other reviews.
6 And we excluded participants with chronic
7 disease, which had already been diagnosed.
8 Next slide.

9 So our first question: what is the
10 relationship between intake of animal protein
11 products and colorectal, prostate, and breast
12 cancer; type 2 diabetes; cardiovascular
13 disease; hypertension; and body weight. I
14 want to note the note on the bottom there that
15 milk and milk products were analyzed
16 separately and seafood was also analyzed
17 separately, so there are different questions
18 for that that have already been done. So in
19 this we were not looking at those animal
20 protein products. Next slide.

21 So our overall draft conclusion,
22 and I think you will see as we go through here

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1 that draft is in big letters, and we want to
2 make that clear, that these are draft and they
3 should not be thought to be final conclusions
4 at all.

5 So most studies find no
6 association with intake of animal protein
7 products and risk of disease including
8 cardiovascular disease, Grade II, blood
9 pressure and hypertension, Grade II, type 2
10 diabetes, Grade III, and body weight, Grade
11 III. Animal protein intake seems to be
12 related to some cancers including colorectal
13 cancers, Grade II, and pre-menopausal breast
14 cancer, Grade III, but this relationship
15 varies by cancer type and possibly differences
16 in preparation of cooking methods, processed
17 well done meat, and this is a Grade III. So
18 next slide.

19 The animal protein products and
20 colorectal cancer. Draft conclusion:
21 inconsistent positive associations have been
22 reported between colorectal cancer and the

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1 intake of certain animal protein products,
2 namely red and processed meat, Grade II.

3 Review of the evidence, 13
4 studies, and these were prospective cohorts
5 from the U.S., Europe, Australia, Finland,
6 Japan, China and Sweden. Next slide.

7 This I really appreciate the help
8 of our staff, Eve, in putting these together.

9 And as you can see the studies are listed to
10 the left, so all the different studies that
11 are included in this review. And one problem
12 we have with this is that not everyone looks
13 at it the same. So as you can see a lot of
14 times they'll look at total meat, red meat,
15 processed meat, poultry, and there is not a
16 consistent way of doing this. You are going
17 to see some of these categories will have
18 nothing in them because they didn't look at
19 that.

20 The way this table is designed
21 too, if - on the bottom there you can see if
22 there's a positive association, you will see a

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1 plus, an inverse association, a negative, or
2 no association will get a circle with a line
3 through it.

4 As you go down you can see that
5 for total meat it's fairly - there doesn't
6 seem to be much going on there; you see a
7 little bit with different types. Going down
8 red meat the same thing. There is no - you
9 can see a few studies where you get a positive
10 with colorectal cancer, sometimes with just
11 one type rectal cancer, not colorectal. So
12 there are inconsistencies. In some of these
13 studies too they'll sometimes actually look at
14 the type of meat. So is it beef, is it
15 hamburger, ask those types of questions.

16 Go down processed meat, you can
17 see the other kind of confusing issue, and
18 sometimes you will see a relationship with
19 different places of the cancer, whether it's
20 distal cancer. You will see some
21 relationship. Sometimes you will see it in
22 men as opposed to women, and if you go over to

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1 the right looking at poultry, also fairly
2 inconsistent findings. Some studies look at
3 eggs, some look at chickens, some look at
4 overall poultry. So a little bit of - some.
5 No inverse relationships at all. No
6 relationships at all, but not much going on
7 there in that category. Next slide.

8 Draft conclusion for prostate
9 cancer: there is little evidence from
10 prospective cohort studies that animal protein
11 products are associated with prostate cancer
12 incidence, this is a Grade III. Six articles,
13 and all were prospective cohort studies from
14 the U.S. Next slide.

15 Same type of table that you looked
16 at before except it is for prostate cancer.
17 The studies are listed. These are all U.S.-
18 based studies, and same thing with different
19 types of meat, total meat, red meat, processed
20 meat, poultry. In general you don't see -
21 very few positives here. Most of the circles
22 have lines through them. A couple of things

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1 are different. If you look at the different
2 categories, sometimes with different cancers.

3 So advanced metastatic cancer, you see a
4 positive. Different - black men only, lunch
5 meats. There are differences. But overall
6 very little going on here. Next slide.

7 Breast cancer, animal protein
8 products. The draft conclusion: cohort
9 studies show little association between intake
10 of animal protein products and overall breast
11 cancer risk, although animal protein intake
12 may alter risk for different types of breast
13 cancer, this is a Grade III. We've found six
14 articles, and they were prospective cohort
15 studies from the U.S. and United Kingdom.
16 Next slide.

17 Same type of table here, looking
18 down there is this health study, PLCO, NIH
19 AARP, Nurse's Health again, the UK prospective
20 study. Going across looking at this data you
21 see some differences with different types of
22 estrogen receptors. Sometimes you will see a

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1 relationship with one but not the other.
2 Going down with total meat, you see in general
3 there are a lot of circles with lines through
4 them but in some cases differences between
5 premenopausal and post-menopausal breast
6 cancer.

7 In general though, not any
8 consistent findings at all. So fairly mixed
9 data, a little bit there on different types of
10 food, hot dogs, but under the processed
11 category, but not a lot going on. Next
12 slide.

13 The type 2 diabetes, our draft
14 conclusion for animal protein products for
15 type 2 diabetes, prospective cohort studies
16 suggest that intake of animal protein
17 products, mainly processed meats, may have a
18 link to type 2 diabetes although results are
19 not consistent. And this is a Grade III.
20 Seven articles were reviewed, and these are
21 prospective cohorts from the U.S. Next slide.

22 Looking at the same type of study,

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1 total meats, red meats, processed meats,
2 poultry. You see some positives here down in
3 total meat in the two studies there,
4 otherwise, let's see; Halton, Nurse's Health,
5 no relationship. Going down to red meat, you
6 can see a couple of positives there for
7 Nurses' Health, one for hamburgers. The
8 Health Professionals differences between
9 different types of meat, so no real
10 consistency, going to processed meat. A
11 little more with different processed meats,
12 not completely consistent, but there are more
13 positives there, and then if you look on the
14 right on the poultry side, you can see how
15 these questions are asked differently, but in
16 general, no real relationship for poultry, a
17 little bit in the Physician's Health Study for
18 eggs. Next slide.

19 Animal protein products and
20 cardiovascular disease. Our draft conclusion:
21 prospective cohort studies show little
22 relationship between intake of animal protein

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1 products and cardiovascular disease, this was
2 in Grade II.

3 We had seven articles that were
4 included, and these were prospective cohorts
5 from the U.S. and Japan. Next slide, same type
6 of table here. You can see a lot of the
7 studies didn't - if there is nothing there we
8 were not able to get that from the study. A
9 little bit - if you look at some of the
10 studies they are done differently. So looking
11 at that - going down three, substituting red
12 processed meat for carbohydrate-dense food,
13 they saw some positive relations there with
14 CAC mortality, and same thing, they did a
15 similar thing substituting poultry. If you go
16 over to the right you don't see anything
17 there. Eggs, no real relationship here. And
18 then, in the top study of only white meat
19 there was CVD mortality only in men. There
20 didn't seem to be a lot going on there. Next
21 slide.

22 Hypertension/blood pressure: our

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1 draft conclusion, no clear association was
2 found between intake of animal protein
3 products and blood pressure in prospective
4 cohort studies, a Grade II. Six articles,
5 these were prospective cohorts in the U.S.,
6 United Kingdom and Spain. Next slide.

7 Again as we go through these you
8 will see a lot of these are the same cohorts.

9 These were endpoints that were measured in
10 studies, so there is lots of repetition in the
11 studies here. Looking at total meat, the only
12 one that shows a little bit of a difference
13 there is the Steffen study, you get a
14 positive; otherwise nothing else. Under total
15 meat, a little bit. Under red meat, certain
16 types, but not consistent. And then poultry,
17 a little bit of that in the Western Electric,
18 but otherwise no real consistent relationship.

19 Next slide.

20 Body weight: animal protein
21 products and body weight, our draft
22 conclusion, existing research finds little

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1 link between meat intake and body weight, this
2 is a Grade III. We only found three articles
3 that got at this question. And there was a
4 different type - these were not prospective
5 studies. There was one, but then there was
6 one randomized control trial and then one
7 cross-sectional study, and as Linda mentioned
8 we tried not to use cross-sectional studies
9 except when we had very little information, so
10 in this case we did include the cross-
11 sectional study. The Mahon study they looked
12 at weight loss with different types of animal
13 protein compared to vegetarian and found no
14 differences in weight loss. These studies are
15 always difficult, because often the calories
16 are controlled. You probably wouldn't expect
17 to see a lot of changes in prospectives.
18 There were inconsistent findings across gender
19 and the types of meat. In some analyses there
20 was a link with red meat and some processed
21 meat, but that was not consistent. And then
22 in the cross-sectional study, there was an

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1 association there. Next slide.

2 So implications: proteins found in
3 animal sources such as meat, poultry, fish,
4 eggs, milk, cheese, and yogurt provide the
5 nine indispensable amino acids and are
6 referred to as "complete proteins." When
7 protein needs are high - so in case of
8 pregnancy, lactation, and childhood - complete
9 proteins in foods are important components of
10 the diet. And if you do not consume animal
11 products you do need to consider complementary
12 protein sources. Obviously, it is very
13 possible to get your protein from plant
14 products, but you do need to know enough to
15 combine those amino acids so, especially at
16 times where protein needs are higher that we
17 are not limiting protein intake. Next slide.

18 So the kind of converse here is
19 the vegetable protein. So in this case -- I
20 don't know if there are any questions, or we
21 can take questions at the end of this protein
22 section. What is the relationship between

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1 intake of vegetable protein, including soy
2 protein, and chronic disease? And as we go
3 through this I want to mention that in this
4 data there were a lot of studies on soy
5 protein and that's why we included that. But
6 we did -- a lot of those studies were done
7 differently. They were feeding studies. So
8 we tried to separate those questions out. So
9 the first question is intake of vegetable
10 protein including soy protein and chronic
11 disease. The second was the relationship
12 between the intake of vegetable protein and
13 blood pressure. And then the relationship
14 between intake of soy protein and blood
15 pressure, body weight and blood lipids. Next
16 slide.

17 Our overall conclusion, fairly
18 long. Little evidence exists that supports
19 unique health benefits of vegetable protein
20 including soy protein on measurable health
21 outcomes. Few studies are available, and the
22 limited data collectively suggest that

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1 vegetable protein does not offer special
2 protection against type 2 diabetes, coronary
3 heart disease and selected cancers, Grade III.

4 Intake of vegetable protein is generally
5 linked to lower blood pressure in both cohorts
6 and cross-sectional studies, Grade II. And
7 some data suggest that soy protein may lower
8 blood pressure in adults with normal blood
9 pressure, Grade III. Soy protein had no
10 advantage over other proteins when consumed in
11 an isocaloric study on body weight. Soy
12 protein may have small effects on total and
13 LDL cholesterol in adults with normal or
14 elevated blood lipids, although results from
15 systematic reviews are inconsistent. Grade
16 II.

17 So our first draft conclusion:
18 few studies are available, and the limited
19 data collectively suggests that vegetable
20 protein does not offer special protection
21 against type 2 diabetes, coronary heart
22 disease and selected cancers, Grade III.

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1 In this review we had seven
2 articles, six prospective cohort studies and
3 one ecological study. Next slide.

4 Selected chronic diseases: this is
5 a - when we get into this dataset there isn't
6 a lot of data in here, so this is - you see
7 some mixing here of diseases. But same design
8 here, down the left all the different studies
9 that we examined. The type of study, and then
10 vegetable protein, did they look at that, and
11 soy protein. So with vegetable protein
12 typically this would be from a food frequency,
13 estimating based on food intake, and then soy
14 protein. Typically those were studies in
15 areas where soy protein is actually consumed
16 in higher amounts than in the U.S.

17 You can see for the Halton, no
18 relationship with CHD and vegetable protein.
19 This other study, the Iowa Women's Health
20 Study, where they did the substitution, you
21 see a little bit of an effect. But overall
22 not. Most of those circles have a line

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1 through them, type 2 diabetes, no
2 relationship.

3 And then over to the soy protein,
4 some differences with pre- and post-menopausal
5 breast cancer, in the Lee study. And if you
6 look at the Japanese study a little bit of
7 difference in stomach cancer, and colorectal
8 cancer, but no differences with heart disease
9 and breast, prostate or lung mortality. Next
10 slide.

11 So, overall, for that, not a real
12 consistent relationship. So if we move on to
13 vegetable protein and blood pressure, our
14 draft conclusion: intake of vegetable protein
15 is generally linked to lower blood pressure in
16 both cohort and cross-sectional studies, Grade
17 II. The evidence reviews six articles, four
18 prospective observational and two cross-
19 sectional studies.

20 So in these types of studies
21 trying to measure vegetable protein with food
22 frequencies, and then looking at either

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1 hypertension, diastolic, systolic blood
2 pressure, so you can see those are summarized
3 on the slide. If we go down to the Wang, the
4 premier study, there were differences at six
5 months but by 18 months there were not
6 differences, for both systolic and diastolic
7 at six months, and for hypertension, there
8 were protective effects of vegetable protein.

9 As you go through that you can see plant food
10 for the Steffen study that was examined.
11 Otherwise - I just lost - okay I'm back, good.

12 So there's enough studies here that suggest
13 that there is a potential relationship between
14 vegetable protein and blood pressure. Next
15 slide.

16 Soy protein and blood pressure.
17 Some data suggest that soy protein may lower
18 blood pressure in adults with normal blood
19 pressure, Grade III. There were five
20 articles, three randomized controlled trials,
21 one prospective cohort and one cross-sectional
22 study. Next slide.

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1 Summarized on this slide you can
2 see that in the He study up on top they found
3 differences. The other Australian study,
4 people that had normal blood pressure, they
5 saw differences in blood pressure. Some of
6 the other studies, the China study, no
7 differences, and then the prospective cohort
8 you see differences, and inconsistent in the
9 other cross-sectional study.

10 So a little bit of data there, but
11 not completely consistent. And remember these
12 are different types of studies where people
13 actually are interviewing and given soy and
14 soy protein. Next slide.

15 So body weight, draft conclusion:
16 soy protein had no advantage over other
17 proteins when consumed in an isocaloric study
18 on body weight, Grade II. Four articles, one
19 systematic review, one randomized control, one
20 randomized crossover, and one cross-sectional
21 study. Next slide.

22 So the systematic review, you can

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1 see, no differences, when they reviewed all
2 the articles. And then the other controlled
3 trials, no differences. And these studies,
4 you will hear more about similar studies in
5 the energy balance area, that if you do
6 control calories, obviously, you wouldn't
7 expect to see differences. Soy protein is no
8 different than other protein sources in
9 affecting body weight. Next slide.

10 Blood lipids: draft conclusion:
11 soy protein may have a small effect on total
12 and LDL cholesterol in adults with normal or
13 elevated blood lipids, although results from
14 systematic reviews are inconsistent, Grade II.

15 So in this there were six articles, four
16 systematic reviews, one randomized controlled
17 trial and one cross-sectional study that was
18 included in the evidence review. Next slide.

19 So the meta-analysis, one of the
20 issues, always, with the meta-analysis when we
21 use these is trying to go back and figure out
22 - we don't want to double count studies, so

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1 depending on which studies are used in these
2 different meta-analyses, it's difficult to
3 sort this out and not double count. But if
4 you look overall, in general the amounts of
5 soy protein that are needed to lower blood
6 lipids are fairly high, too. So typically the
7 usual - the 25 grams per day of soy protein is
8 accepted for lowering blood lipids. So in
9 general, it takes high doses like that to have
10 an effect. There is some concern about - are
11 the isoflavones important, are they the key
12 and in the two - Zhan and - the two second
13 meta-analyses they attempted to sort out the
14 isoflavone question to see how important that
15 was, and that was pretty inconsistent, of, are
16 the isoflavones important, are they the
17 primary part, pretty unclear on that.

18 If you look at the randomized
19 controlled trial with weight loss, we did see
20 some changes but no changes in HDL or
21 triglycerides, and then the cross-sectional,
22 no changes in triglycerides or HDL. Next

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1 slide.

2 So, implications of vegetable
3 protein. To achieve optimal nutrition intake,
4 recommended levels of dietary protein sources
5 must be consumed with protein derived from
6 both animal and plant sources. Our review
7 indicated that intake of vegetable protein is
8 generally linked to lower blood pressure in
9 both cohorts and cross-sectional studies, but
10 obviously this could be due to other
11 components in plant food such as fiber or
12 other nutrients besides protein. Individual
13 sources of vegetable protein have no apparent
14 unique health benefits, so choice of protein
15 sources can come from a wide range of plant-
16 based foods depending on preferred eating
17 pattern.

18 Recommendations to lower calorie
19 intake to combat obesity by increasing plant-
20 based food intake must be linked to cautionary
21 messages to maintain protein intakes at
22 recommended levels. Next slide.

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1 So I think we can take a break
2 here and talk, if anybody has questions about
3 protein before we move on to carbohydrates.

4 DR. RIMM: This is Eric. I have
5 a few questions if I can start. Is that okay?

6 DR. SLAVIN: Absolutely.

7 DR. RIMM: So, what an incredible
8 amount of work! Congratulations on putting
9 that all together, not only in finding all the
10 studies but in presenting it so nicely. I
11 think it was very clear to me, and actually
12 the way you lined things up, it almost made me
13 think some of your conclusions should be
14 stronger.

15 And, for me, some of it was the
16 contrast. You showed the studies for
17 processed meat in diabetes and processed meat
18 in colon cancer, and it looked like almost all
19 of those who had measured it had found a
20 positive association, and a lot of those same
21 studies that looked at blood pressure found
22 absolutely nothing, which makes me think that

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1 the associations for diabetes and colon cancer
2 are that much stronger, and maybe we should
3 have something - I don't know, the diabetes
4 one I think was Grade III evidence, and made
5 me think like it should be Grade II. But I
6 wonder if we should have something in the
7 implications that does point to the fact that
8 it's probably better for animal protein
9 sources to come from sources that are not
10 processed. I mean, I don't know if we can do
11 that. And also I know, sitting in the back of
12 my head is, I just heard a meta-analysis at
13 the AHA epidemiology meeting on processed meat
14 and coronary heart disease, again sort of
15 pointing out the fact that the fat content was
16 much less important than the fact that the
17 meat was processed or not. And this is I know
18 a meta-analysis that was just accepted that
19 also points to the same thing, that there is
20 not just the fact that it has protein and it
21 has fat, but there is something about the
22 processing of the meat.

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1 I don't know, did you get a sense
2 for that? It was just the diabetes one that
3 was so striking to me, that in the processed
4 meat column almost everything was positive.

5 DR. SLAVIN: I think that as we
6 went through this data it would be nice if
7 studies used the same ways of looking at it.
8 Because what goes into processed meat, and
9 what's different between processed meats
10 versus unprocessed meats. And as you
11 mentioned, it probably has nothing to do with
12 fat. Is it sodium? Is it other things that -
13 and overall we didn't see that processed meats
14 came out across the board as potentially - you
15 know, we talk about lighting up the screen.
16 But we may need to go back and think that
17 through, because there may be certain diseases
18 where there is more of a relationship.

19 DR. RIMM: I think it is a
20 challenge, especially when you look at cohorts
21 across the world, the way people measure
22 things, and what does it mean to have

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1 processed meat in China versus Europe versus
2 the U.S.? The constituents are probably
3 different. I don't know. There is clearly
4 never going to be a trial. It's not going to
5 be a four-year trial of processed meat versus
6 non-processed meat. So maybe the best
7 evidence we get is from observational studies.

8 And it's only because of the contrast that I
9 felt - we see it for a few diseases and you
10 don't see it for a few others. So if it
11 really was just confounding by processed meat
12 eaters, then we may be seeing, as you say,
13 lighting up across all diseases. But that
14 doesn't seem to be the case. Which just made
15 me think that diabetes and colon cancer, maybe
16 we should be a little stronger about our
17 implications and our grade.

18 DR. SLAVIN: I appreciate that,
19 and in thinking of what comes out in both fat,
20 fatty acid subcommittee too - I don't know
21 with diabetes what kind of things you found,
22 in bringing this stuff together. Because I

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1 think when we focus in on macro-nutrients,
2 sometimes we miss things.

3 DR. RIMM: Yes. Well, we will
4 get to that when we talk about it. It's not
5 as focused on diabetes. There were some
6 differential results from diets among
7 diabetics, but not necessarily as much looking
8 at instance of diabetes.

9 DR. SLAVIN: Okay.

10 DR. VAN HORN: I might also add -
11 this is Linda - that that is in fact one of
12 the reasons why the total diet chapter that we
13 alluded to earlier will become so relevant, I
14 think, because we don't pick and choose our
15 diet around, well, I would like to avoid
16 diabetes today, but tomorrow I think I will
17 risk this. We have to put this all into
18 context, and recognize that, I was thinking,
19 even as you were talking about the absence of
20 evidence in regard to vegetable protein, that
21 doesn't in any way negate the value of
22 vegetable protein in a diet that is attempting

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1 to maximize things like dietary fiber for
2 example. So I think Eric's point is well
3 taken, and as the rest of these subcommittees
4 present their data, it's probably important
5 for all of us to think about what implications
6 some of these conclusion statements have in
7 terms of translating this to a total diet
8 concept.

9 DR. FUKAGAWA: This is Naomi. A
10 point of clarification. What - how are we
11 defining process? Both in what Eric just said
12 and with respect to this report?

13 DR. SLAVIN: Well, I think in
14 these studies, Naomi, that was up to the
15 investigator. So it's typically people are
16 counting luncheon meat, they're counting hot
17 dogs, meats that are processed. And I'm sure
18 as the meat industry has changed, there is
19 more turkey, poultry, than there was 20 years
20 ago, so I don't think it's a static thing.
21 And I don't know - Eric, can you help me out
22 on this? Because having been involved in

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1 those types of studies, I assume salami,
2 bacon, those would fit in that category?

3 DR. RIMM: Yes, I mean a lot of
4 it just depends on how the questionnaire is
5 designed, and when you have a question that
6 just says, red meat or pork, that is not
7 processed. But then you have questions on hot
8 dogs and other - I mean, our question that we
9 use in our cohorts specifically says I think
10 hot dogs and other processed meats. And then,
11 it's also, deli meats are also considered
12 processed meats because most of them are not
13 just turkey cooked and cut, most of them are
14 truly processed with salt and nitrates and
15 things like that. So those are the two or
16 three things that we put together. And I
17 think a lot of other questionnaires are
18 designed the same way, you try to separate out
19 the - beef, pork, and lamb that is served as a
20 main dish separately from those that are
21 processed.

22 DR. SLAVIN: Processed or

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1 preserved in some way, then.

2 DR. RIMM: Correct.

3 DR. CLEMENS: I appreciate that
4 comment, Naomi. I think as we go forward that
5 this very important question is certainly on
6 the minds of many consumers. As the USDA
7 attempted to define minimally processed it
8 didn't do that adequately. So the FDA has not
9 defined processed foods. So it may be
10 beneficial for our consumers that we put a
11 little bit of effort into trying to define or
12 at least clarify what processed might be. And
13 I appreciate your remark, there, Eric, that in
14 fact the processed word is actually being
15 modified as we go down the line here, and
16 that's beginning to change. Unfortunately
17 those changes do not necessarily reflect what
18 we are able to see in the clinical studies.

19 DR. ACHTERBERG: And this is
20 Cheryl. What I wanted to circle back to and
21 address Eric's initial questions is, actually
22 very few of these studies included any

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1 separation of processed meat from other fresh
2 meat, and in another category that we haven't
3 talked about or mentioned yet is barbecued
4 meat, smoked meat, so people measured
5 differently, they measured different things,
6 and there aren't many data, and that's why we
7 have a lower grade.

8 DR. SLAVIN: I appreciate that,
9 Cheryl, and also this idea of grilled meats
10 and all that relationship to carcinogens.

11 DR. RIMM: This is Eric again,
12 I'm not clear on what Cheryl was pointing out.

13 I think most of the studies that look at
14 processed meat do separate it out, but you are
15 right, if someone says they eat red meat, you
16 don't know whether it's cooked on the grill or
17 not. The assumption is that when they bought
18 it it was not processed. So there are some
19 aspects of cooking methods which we don't know
20 about even though people ask about it. That's
21 really - could be measured. But I think most
22 of the cohorts here do separate out the

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1 purchase of processed meat versus purchasing
2 meat that is not processed.

3 DR. SLAVIN: But I think Cheryl's
4 point is that when we looked at all the
5 studies there was no real consistent way of
6 getting at that, but then when you look at
7 those tables you see a lot of blanks, because
8 it wasn't asked in every study.

9 DR. RIMM: Okay, that I
10 understand.

11 DR. SLAVIN: That's how you could
12 get a higher grade.

13 DR. APPEL: This is Larry. I
14 have a few questions, comments. First of all
15 this is a tremendous body of work, very
16 impressive. But first is right up front,
17 animal protein products, it seems like you
18 focused on meat, yet in the implications then
19 you mentioned milk, yogurt and other things.
20 And I'm wondering whether you should just
21 really replace the term animal protein
22 products with meat. And I assume that the

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1 health issues related to milk and dairy are
2 going to be covered elsewhere.

3 DR. SLAVIN: Right, milk and
4 dairy are in a separate section. Fish is in a
5 separate section. But animal protein really
6 included everything else. So poultry, eggs,
7 anything else in that category.

8 DR. APPEL: But shouldn't you use
9 meat, then, rather than animal protein
10 products, which is really more generic?

11 DR. SLAVIN: Well, that is the
12 way we did the search, though. So go back in
13 our search term, we tried to completely open
14 it up, both the vegetable protein side and the
15 animal protein, because all these studies are
16 done differently. How do you capture that?
17 So anything - eggs, those would be all in our
18 search. So that's just the way the question
19 was done. We could go back and see that
20 probably what the percentage of meat; it's
21 probably pretty high. Obviously poultry is
22 going to be a fairly high amount of what we

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1 found.

2 DR. APPEL: Yes, there just seems
3 to be a disconnect.

4 A second issue is - has to do with
5 sort of the issues related to blood pressure
6 and protein. I notice for example with soy
7 that you still are mostly cohort studies. But
8 there are actually a fair number of trials in
9 this area, and also there are a fair number of
10 trials with mixed protein, meat and vegetable
11 protein. I know one that I've led Omni Heart.

12 So I'm just - were those just excluded?
13 Because I think there are actually quite a few
14 clinical trials of soy protein.

15 DR. SLAVIN: I think the ones -
16 anything that was in a meta-analysis that they
17 would have been excluded only for that reason,
18 if they had already been reviewed and included
19 in any of the systematic reviews or meta-
20 analyses. Otherwise, if we go back and look
21 at our search terms, if there was blood
22 pressure and animal protein, by any of the

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1 ways we got there, it should have come up.

2 DR. APPEL: Okay.

3 DR. SLAVIN: You could go see why
4 it was and include it.

5 DR. APPEL: And then what about
6 total protein? Because as I said, perhaps the
7 biggest study of protein and blood pressure
8 was done Omni Heart. And that was - I think
9 most of the protein actually came from
10 vegetable protein, and there was an effect of
11 total protein on blood pressure.

12 DR. SLAVIN: Yes, you know I
13 think the way we did this search, and since it
14 had never been done before we probably - the
15 next time we might be able to do a better job.

16 But we specifically looked at animal proteins
17 and we looked at vegetable proteins. I think
18 though if a study only looked at total protein
19 and blood pressure it should have come up, but
20 maybe Eve or someone can help me out here if
21 we would have missed that. And you are right
22 that there are probably some studies - you

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1 know a lot of those studies too, those high
2 protein studies with weight loss, typically
3 you would - you would expect to see a
4 difference in blood pressure. But we may not
5 have caught those if it was just a protein
6 study, sometimes a carbohydrate or some kind
7 of design like that.

8 DR. VAN HORN: I do think Larry
9 raises a very important point though in regard
10 to meta-analyses which we actually discussed
11 in some of the other subcommittees, and that
12 is that studies that have a certain amount of
13 weight in terms of their quality and their
14 design, et cetera, et cetera, could
15 potentially get sort of lost in the shuffle if
16 only being viewed within a meta-analysis. So
17 it could very well be that we should,
18 especially with - Omni Heart, but there may be
19 other landmark studies kind of that nature
20 that we might want to zero in on and make sure
21 we haven't sort of obliterated the strongest
22 messages from those major studies just by

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1 virtue of the approach that meta-analyses
2 take.

3 DR. APPEL: Yes, and there is
4 also a related issue when you're dealing
5 mostly with cohort studies, and that is it
6 sort of treads on the approach to analysis,
7 which is that at least when we do clinical
8 trials it's a substitution, and I know there
9 are some cohort studies that present their
10 data through substitution, like substituting
11 carbohydrate for protein, but I think
12 especially in the context of trying to avoid
13 messages that increase confusion it really is
14 - I think it's more of a substitution
15 question. You are eating more protein instead
16 of something else as an energy source. And I
17 know that in the controlled feeding studies
18 that is exactly what we do. In Omni Heart it
19 was substitution of carbohydrate with protein.

20
21 DR. SLAVIN: I think I would
22 agree that any studies we have missed should

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1 definitely be part of our hand search and
2 included. We could not find studies where the
3 question was a randomized controlled trial
4 where people compared protein balance, animal
5 versus vegetable. There's lot of descriptive
6 studies, there are lots of review articles
7 with health benefits. But there really aren't
8 studies that have looked at that. I think
9 especially with lower calories one of the
10 concerns is because protein quality is not as
11 high as we want people to eat fewer and fewer
12 calories, protein quality is an issue too. So
13 to have a study where you actually compare
14 animal protein to vegetable protein in a
15 randomized controlled trial, we didn't really
16 find anything like that. There were a few
17 with the soy, but there really isn't anywhere
18 where the question is vegetable protein.

19 Most of our data really is the
20 cohort study.

21 DR. PEREZ-ESCAMILLA: Can you
22 hear me?

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1 DR. SLAVIN: Yes, now we can,
2 Rafael, go ahead.

3 DR. PEREZ-ESCAMILLA: Joan, thank
4 you for a wonderful presentation. My question
5 is about how do these conclusions regarding
6 animal and vegetable protein and cancer
7 compare with the conclusions reached by the
8 World Cancer Research Forum Report that was
9 widely disseminated a couple of years ago?

10 DR. SLAVIN: We compared our
11 results to their results, and they, if you
12 look at a lot of theirs are certain types of
13 foods; there were some inconsistencies also.
14 They found similar results. They also
15 included cross-sectional studies so there are
16 some differences in their summary table if you
17 look at the picture where they look at all
18 different cancers and different foods and
19 eating patterns, I don't think they found big
20 differences from ours. I guess I don't see a
21 big inconsistency, and I know as our Committee
22 has discussed that we would use that, make

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1 sure in our section that we can refer to that
2 just to make sure we are not giving out
3 inconsistent results.

4 They did processed meats, fruits
5 and vegetables. There is a lot of overlap
6 with what we looked at, but I think that
7 overall - different cancer studies do find
8 inconsistencies.

9 DR. APPEL: This is Larry again.

10 I'm wondering, I don't know if it's the
11 grading or the conclusion, but I'm seeing some
12 differences in how the conclusions are phrased
13 that leads to different impressions, and even
14 where Grade II comes across as less strong
15 than some Grade III recommendations. Like the
16 colon cancer one starts off with an
17 inconsistent positive association, that's
18 Grade II, and later on for like the animal
19 products in breast cancer cohort - maybe that
20 isn't the best one, the diabetes one -
21 prospective cohort studies suggest that intake
22 may have a link which is a Grade III.

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1 And we're probably not supposed to
2 wordsmith, but I do see some sort of
3 disconnect between grade level and sort of the
4 phrasing.

5 DR. SLAVIN: I think Larry, we've
6 had discussions in committees chime in here
7 and help me out, that we've struggled with
8 that, and a lot of times the Grade III is just
9 that there is less data, and it's still fairly
10 inconsistent but there were just fewer studies
11 to base it on, so some of those differences
12 between II and III are based more on the
13 amount of data than the consistency of
14 finding. But Cheryl maybe you can help me
15 out, Linda, I'd be happy to take any comments
16 or reconsider any of the grades. I think that
17 these are draft conclusions, so we're
18 absolutely open to input on that.

19 DR. VAN HORN: And I think this
20 goes along with what I was trying to get
21 across earlier which is as we march through
22 each of the subcommittees, I have a feeling

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1 that this concept will come up again, and
2 therefore we should be conscious of it and try
3 not only within Committee reports but across
4 them try to apply equal judgment in
5 interpreting some of these results which is
6 not easy. But I think we will hear it
7 frequently throughout the day, and perhaps we
8 can try to fine tune our precision in
9 qualifying one against the other.

10 DR. ACHTERBERG: This is Cheryl
11 Achterberg. I might offer too that I think
12 this subcommittee was pretty conservative with
13 its grades, because there were very few
14 randomized controlled trials, and we tended to
15 stay with a Grade II without studies of that
16 design. So there may be some variation for us
17 to work out today in the way that different
18 subcommittees generally graded certain kinds
19 of designs.

20 DR. WILLIAMS: This is Christine.
21 Joanne, thank you for that excellent
22 presentation. I just had a few questions

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1 about the soy protein and blood pressure and
2 body weight and blood lipids. It looks like
3 all the data related to adults; is that true,
4 were there no pediatric studies?

5 DR. SLAVIN: That is a good
6 question. We probably focused on adults, and
7 I don't know if we excluded - Eve or somebody
8 help me, I'm not sure if we wouldn't have
9 picked up - I doubt that there are many
10 feeding studies on kids at all would be my
11 guess, but whether we would not have picked
12 those up, I think we would have. So yes, you
13 are right, what is out there are mostly adult
14 studies.

15 DR. EVE ESSERY: Joanne, this is
16 Eve.

17 DR. WILLIAMS: It should be clear
18 in the conclusion statements that it only
19 relates to adults.

20 DR. SLAVIN: Did you hand me a
21 note? Whether kids would have been excluded?

22 DR. ESSERY: Sorry, Joanne, can

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1 you hear me now?

2 DR. SLAVIN: I can.

3 DR. ESSERY: This is Eve.
4 Children were not excluded in this search, so
5 they would have been included, and there just
6 were very few studies in that group that were
7 included.

8 DR. SLAVIN: Thank you. So the
9 search wasn't specific just to adults. That
10 conclusion statement can be worded to address
11 adults since that was where your data was, not
12 necessarily specific to adults.

13 DR. SLAVIN: And Christine, are
14 you thinking of like recommendations for kids?

15 DR. WILLIAMS: Well, I agree, I
16 think there are very few studies, but I just
17 wondered if you had identified any data if
18 there were cross-sectional.

19 DR. ACHTERBERG: I don't recall
20 any in the search. I read through all the
21 articles as well, and I don't recall any about
22 children, though they were not excluded.

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1 DR. SLAVIN: And I do think that
2 is probably an important research
3 recommendation that we want overall with fiber
4 and some of the other recommendations, be
5 increasing plant food and potentially plant
6 protein to make sure there are no other - are
7 there some positives, are there some
8 negatives, and there probably needs to be more
9 studies or cohorts where people are followed
10 to make sure protein quality and growth are
11 not impacted.

12 DR. WILLIAMS: It might be
13 included in research recommendations?

14 DR. SLAVIN: Right.

15 DR. VAN HORN: All right, well,
16 we should probably move forward unless there
17 are other comments.

18 DR. SLAVIN: I do want to note
19 that in our protein chapter, the introduction,
20 there is a lot more background on protein, so
21 today we are just discussing our NEL
22 questions. So the chapter on protein will

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1 have a lot more discussion on protein and kind
2 of this discussion as calories go down,
3 protein - we have an RDA for protein and it's
4 based on our body weight. The percentage of
5 protein in the diet will potentially go up as
6 people - and I know we had a lot of public
7 comment on the importance of higher protein
8 diets, and increasing protein and in our
9 review we looked for any potential on high
10 protein diets, so I think that will also be in
11 our chapter.

12 Any other protein questions before
13 we go to carbohydrates?

14 (No response.)

15 DR. SLAVIN: All right,
16 carbohydrates. I don't know why we took on
17 proteins, because we had too much to do on
18 carbohydrates, but we did. We have a lot of
19 carbohydrate topics, and some of the other
20 carbohydrate topics are already presented at
21 the other public meetings, but what is left to
22 present today, health benefits of fiber,

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1 relationship between whole grain intake and
2 selected health outcomes, in adults,
3 association between intake of sugar-sweetened
4 beverages and energy intake and body weight
5 and energy intake, we'll talk about children
6 in that same question. How are non-caloric
7 sweeteners related to body weight? What is
8 the impact of liquids versus solid foods on
9 energy intake and body weight? What is the
10 role of carbohydrates, fiber, protein, fat and
11 food form on satiety, and the role of
12 prebiotics and probiotics?

13 And I want to mention that, as we
14 go through these we'll talk about the ones
15 that were done with the NEL review and some
16 that were not. And part of the reasons those
17 decisions were made was, workflows really for
18 our Committee, and kind of net gain in doing a
19 NEL review. So we were limited in how many
20 NEL reviews we could do, so some of these
21 questions were looked at with the literature
22 review, and therefore they will not be graded.

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1 So as we go through these topics, you will
2 see some of them do not have a grade. When we
3 get to those, and that is because they were
4 not done with the NEL topic.

5 Next slide. So what are the
6 health benefits of dietary fiber? We actually
7 addressed this using a non-NEL review of the
8 literature and the reason that decision was
9 made is that the American Dietetic Association
10 had conducted a NEL review of dietary fiber
11 and health that was published in 2008, so we
12 are essentially going to update the data from
13 that since that had already been published in
14 2008, we didn't want to go back and redo all
15 that.

16 So draft conclusion - this is not
17 a NEL conclusion - dietary fiber from whole
18 foods, including whole grains, protects
19 against cardiovascular disease and obesity,
20 and it's essential for digestive health. Not
21 all isolated fiber or functional fiber have
22 proven physiological effect and need to be

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1 evaluated in randomized controlled trials.
2 Next slide.

3 The way we set this up too, in the
4 chapter there is a discussion of carbohydrates
5 and we kind of entered into first dietary
6 fiber, and then we moved into whole grains,
7 and the whole grains was done with a NEL
8 review, and the questions that were asked with
9 the NEL review is: what is the relationship
10 between intake of whole grains and first,
11 incidence of cardiovascular disease; second,
12 incidence of type 2 diabetes; and third,
13 incidence of - or body weight or measures of
14 adiposity.

15 Next slide. So this question was
16 addressed by a 2005 DGAC. So the answer - the
17 NEL question, we went back to articles
18 published in 2004, and all study designs were
19 originally included in the searches, and this
20 was basically to get as many studies as
21 possible. Later the cross-sectional studies
22 were excluded when we had sufficient evidence

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1 from stronger studies. So we started out with
2 a very open search to get as much as possible,
3 but later - we went with the strongest designs
4 we could find.

5 Original articles included meta-
6 reviews or meta-analyses were then excluded,
7 and also we excluded studies that only
8 considered participants diagnosed with chronic
9 disease, hyperlipidemia, hypertension, other
10 diseases. Next slide.

11 Our overall draft conclusion:
12 whole grain intake which includes cereal
13 fiber, protects against cardiovascular
14 disease. Whole grain intake is also
15 associated with lower blood pressure, Grade
16 II. Evidence suggests that consumption of
17 whole grains is associated with reduced
18 incidence of type 2 diabetes, the lack of
19 randomized controlled trials limits a stronger
20 conclusion. Grade III. And intake of whole
21 grains and grain fiber is associated with
22 lower body weight, Grade III. We'll go

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1 through each one of these questions
2 separately.

3 The first is, whole grains and
4 cardiovascular disease. Our draft conclusion:
5 whole grain intake which includes cereal
6 fiber, protects against cardiovascular
7 disease. Whole grain intake is associated
8 with lower blood pressure in prospective
9 cohort trials. Limited RCTs find little
10 differences in surrogate CVD endpoints when
11 whole grains are consumed. Grade II
12 evidence.

13 For review of the evidence, we had
14 seven articles, two systematic reviews, one
15 meta analysis, three prospective cohorts and a
16 randomized controlled trial.

17 As we go through this, these
18 studies are very different, so I'm going to
19 talk probably in a little more detail than I
20 have in other studies just to give you an idea
21 of kind of the differences here. So the
22 DeMoura study up on top was a systematic

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1 review. And what they did is they went in and
2 used only the FDA definition that is accepted
3 for whole grains, which is 50 percent of
4 weight of the product has to come from whole
5 grains, and they reanalyzed the data based on
6 that, and then they actually did an expanded
7 definition where they included a broader
8 amount of whole grain and evaluated the data
9 based on that.

10 And as we go through this, one of
11 the concerns there've been with whole grains
12 is that there aren't accepted definitions, and
13 there aren't good ways of measuring whole
14 grains, so the data on whole grains if you go
15 back to when they were first measured in
16 epidemiological studies, typically there is a
17 -- 25 percent is considered what is a whole
18 grain. Other people have newer studies, and I
19 know Eric, some of the newer studies you guys
20 have done actually have grams of whole grain,
21 so as this field has moved on there have been
22 a lot of different ways of approaching whole

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1 grains. So therefore these studies tend not
2 to be easily compared because of how they look
3 at whole grain.

4 But you can see in that first
5 study there when they used the FDA definition
6 of whole grains they found much less; they
7 found much less of a protective effect. So
8 it does point out that deciding on a
9 definition of whole grains, and the
10 measurement of whole grains is really
11 importance.

12 The systematic review, the Kelly,
13 they looked at some results on cholesterol and
14 saw some differences with whole grain intake.

15 The other Mellen analysis looking at CVD,
16 addressing CVD, finding a protective effect.

17 The prospective cohort, differences,
18 protective effect, of Flint, and this is on
19 hypertension; Eric can help us out on this
20 one. The protective effect for hypertension.

21 The Nettleton, incidence heart failure. So
22 if you look at the epidemiological studies, if

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1 you use the definition, and I know, the Flint
2 study they actually used grams of whole grain
3 so that was different, and I think that was
4 probably a better measure, but using the
5 accepted way of sorting whole grains, you see
6 pretty consistent effects, if you go up and
7 use the 50 percent of FDA definition then you
8 don't see a protective effect.

9 And then there is a recent
10 randomized controlled trial where they
11 actually gave whole grain, so that is - there
12 are very few randomized controlled trials of
13 whole grains, but this WHOLEheart study. In
14 this study they put people on three servings
15 of whole grains at the beginning, and then
16 they actually upped the whole grain serving.
17 So these were people that were considered high
18 risk for cardiovascular disease. This was
19 done in the UK, and they were randomized to
20 whole grains to see if there were any
21 differences in different lipid profiles. And
22 in this study there were no differences in

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1 lipid profiles, in the two different amounts
2 of whole grains we were given. So first 60
3 and then they went up to 120 grams per day for
4 eight more weeks and in this study no effect
5 on blood lipids.

6 So that's the cardiovascular, and
7 that is where there is the most data for whole
8 grains. And I don't know if people want to
9 ask questions. We can ask questions when we
10 get done with all of whole grains, since we
11 want to take a break then. Next slide.

12 So for diabetes, the draft
13 conclusion: evidence from prospective cohort
14 suggests that consumption of whole grains is
15 associated with reduced incidence of type 2
16 diabetes. The lack of randomized controlled
17 trials limits a stronger conclusion. Four
18 articles, one systematic review with a meta-
19 analysis, and then another systematic review
20 alone, one prospective cohort, and one
21 randomized controlled trial. Next slide.

22 This, the one up on top was kind

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1 of a systematic review and a meta-analysis
2 that was put together. There is a protective
3 effect you can see in the red column there.
4 The other systematic review, where they had
5 one randomized control, and this is a little
6 hard to look at just because there is some
7 overlap here, so we attempted to sort that out
8 as best as possible. There was a protective
9 section on diabetes, the prospective cohort,
10 looking at whole grain ready-to-eat cereal,
11 there was a protective effect on diabetes.
12 But again, like the WHOLEheart study, it is
13 the only randomized controlled trial, and in
14 these high-risk subjects, giving them whole
15 grains in two doses over a fairly long time
16 period had no effect on fasting glucose or
17 insulin. Next slide. Body weight or
18 adiposity. Draft includes, a intake of whole
19 grains and grain fiber is associated with
20 lower body weight, although few RCTs or
21 prospective cohort studies are published in
22 this area, Grade III.

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1 Eight studies, one systematic
2 review, with meta-analysis, one systematic
3 review, a nonrandomized crossover trial, two
4 randomized trials, and three cross-sectional
5 studies. And I want to note here that the
6 cross-sectional studies were included just
7 because we didn't have a lot of data, but we
8 tried with our Committee to give them less
9 weight in our overall grades and conclusions.

10 Next slide.

11 So looking at this, the systematic
12 reviews, you can see there are positive
13 effects of whole grains; the Behall study was
14 a nonrandomized crossover trial, and in some
15 of the studies, fairly small datasets, but
16 body weight was actually decreased with the
17 whole grain treatment, and some of these
18 studies too, like these are oat studies or
19 wheat studies, that are whole grain, that were
20 given. The Katcher is a study where they
21 actually gave - there are no differences in
22 body weight between whole and refined, but

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1 there were differences in abdominal fat and in
2 this study, similar to other studies, both
3 groups lost weight. So they randomized people
4 to both a whole grain or a refined grain. So,
5 overall, everybody lost weight, but there were
6 differences in abdominal fat between the two
7 groups.

8 Same thing for the Brownlee study
9 you've already seen, the third time through.
10 But in this study they followed these people
11 and nothing changed as far as BMI, they
12 measured BMI, percent body fat and waist
13 circumference, and there were no differences.

14 And then the cross-sectional study. So in
15 these cross-sectional studies you'd see
16 differences with body mass index, with whole
17 grains compared to not whole grains.

18 So next slide. Whole grains,
19 something on implications. Typically in these
20 studies there is a lot of overlap with these
21 studies looking at grain fiber or whole grain
22 depending on how they ask the question, and a

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1 lot of these cohort studies there are data
2 that has been presented both for grain intake,
3 whole grain intake and grain fiber intake, and
4 typically grain fiber is a stronger predictor
5 than whole grain in these epidemiological
6 studies, although there is a lot of overlap,
7 just because of how those things are measured.

8 This may be due to the inability
9 to define whole grains and measure whole grain
10 content of food. So there isn't a consistent
11 approach to this. There has been change as
12 interest in whole grains has gone on, so
13 looking at how people evaluate whole grain
14 intake in studies has - would have been nice
15 right from the beginning to accept some ways
16 of doing that and move forward with that, but
17 that is not the data that is out there. So
18 some of it may have to do with this inability
19 to define whole grains at that recent
20 reanalysis based on 50 percent; then, if you
21 use a different standard for whole grains you
22 cannot see an association.

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1 The strongest data is grain fiber,
2 less cardiovascular disease, type 2 diabetes
3 and obesity. The unique benefits of whole
4 grain versus grain fiber is really lacking,
5 and so the idea with whole grains is just the
6 whole thing beyond the fiber, but if you look
7 at the epidemiological data, hopefully Eric is
8 going to help me out here at the end, and give
9 me some ways of thinking about this.

10 So based on our review, grain
11 fiber is pretty consistent protected in these
12 large cohort studies, and whole grains
13 typically don't have anything beyond that.
14 The randomized controlled studies that have
15 been published - and there are very few that
16 are out there - but they don't show measurable
17 health outcomes of whole grain interventions
18 compared to refined grain intervention. Next
19 slide.

20 I don't know, does anybody want to
21 ask a whole grain before we - I know we have
22 time at the end, to talk about other

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1 carbohydrates, but I'd really like to take a
2 break now if anybody has a fiber or whole
3 grain question that we could address now.

4 DR. RIMM: Joanne, is there
5 anything unique about that trial that was just
6 published? It seems like that one was
7 throwing a lot of cold water. And sorry, this
8 is Eric Rimm. Was it very highly processed
9 whole grain? I think that is an issue that's
10 come up is that it's kind of hard to judge
11 differences in whole grains just because
12 sometimes they are highly processed, and the
13 sugar is more exposed to absorption. I don't
14 remember seeing that trial; I haven't read it.

15 So was there something unique about that
16 trial?

17 DR. SLAVIN: I believe when it
18 was set up, it was free living people and it
19 was whole grains that were - they had a whole
20 list of things and they were given them, so I
21 think they had some choice. But whole grain
22 cereal, whole grain snack foods, whole grain

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1 breads compared to refined grains. So it was
2 set up that way that they would take that -
3 and actually the amounts they were given are
4 fairly significant, so it wasn't like they
5 didn't get any. But people would come in,
6 they were counseled to take in these whole
7 grains, but they were commercially available
8 whole grains; that is my impression of how
9 that study was conducted.

10 So one of the concerns, I was at a
11 meeting where it was presented, and they said,
12 you know, just adding whole grains to the diet
13 you wouldn't expect people to lose weight,
14 because they are eating more whole grains, you
15 know, rather than substituting for other
16 things.

17 DR. RIMM: Oh, so the trial
18 wasn't set up for it to be a substitution?

19 DR. SLAVIN: I think that was the
20 goal that they were supposed to do that, but
21 that when they looked at food intake, people a
22 lot of times weren't eating fewer calories.

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1 DR. RIMM: I think that is a
2 point that Linda has talked about many times
3 during these meetings is that, it's nice to
4 talk about things that are healthy but if we
5 just keep on adding calories then of course
6 there is not going to be great benefit from
7 it.

8 DR. SLAVIN: Right.

9 DR. RIMM: I mean, one of the
10 benefits of whole grains is it's supposed to
11 be satiating. If that didn't work in these
12 studies, it means either they are not
13 satiating, or there was something about these
14 over-processed whole grains that ultimately
15 led to people absorbing more sugar quickly.

16 DR. SLAVIN: Yes, and I think
17 from that - although they did, in their
18 defense, they measured a lot of endpoints; it
19 was very involved - the study was funded by
20 the UK standards - so it was a very large
21 study, and they measured a lot of endpoints.
22 I think it was pretty well run. But you know

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1 it's actually pretty hard to lower blood
2 cholesterol even with oat bran or things, we
3 don't lower cholesterol without a fairly large
4 intake.

5 DR. RIMM: No, I think I agree,
6 and the effects you see from oat bran
7 generally are relatively small. They can be
8 important at a population level but they are
9 relatively small, so I think you are right. I
10 wasn't questioning the integrity of the study.

11 It sounds like it was a well-run study. The
12 issue is if you run a trial where you give
13 people free food, it doesn't mean it's going
14 to magically make things change.

15 DR. SLAVIN: No, and then the
16 Katcher study too, that study was published in
17 AJCN, and in that study they measured refined
18 versus whole, and everybody, when people were
19 on the intervention, everybody improved, so
20 they all lost weight, so in those types of
21 designs too typically - because carbohydrates,
22 and this comes out kind of in the beginning of

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1 our chapter, that a lot of the data on
2 carbohydrates is across the board pretty good.

3 Carbohydrates, no matter how you measure
4 them, tend to be linked to lower body weight.

5 So even if you give people refined grains in
6 these studies, you see similar changes in
7 endpoint and body weight.

8 DR. RIMM: So does your Committee
9 think - I mean, I'm just sort of thinking down
10 the line, and maybe - I hope this is not out
11 of line - but the current dietary guidelines
12 say, try to eat half your carbohydrates or
13 half your grains as whole grains. Do you
14 think there is enough evidence now or enough
15 new evidence that we should make a stronger
16 case about eating as much as possible of whole
17 grains?

18 DR. SLAVIN: We have two - the
19 modeling exercise, and you will hear it from
20 Shelley when we talk, that because refined
21 grains are fortified with folic acid, I don't
22 think we would recommend more than half, and I

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1 also think based on some of this newer data
2 that the idea, if we are giving out, telling
3 people to eat more whole grains and there is
4 no more fiber in those whole grains, or there
5 is not a significant amount of whole grain in
6 those products, we are probably misleading
7 people. So if we are going to have
8 recommendations for whole grains we are really
9 going to have to tighten up what is a whole
10 grain. That is kind of my read on this area
11 is that, now that we have whole grain snack
12 foods, then telling people to eat more, green
13 light, is not a good recommendation. Overall,
14 people need to eat fewer calories, whether
15 they are whole grains or not. We don't want
16 to give people the impression that because
17 it's whole grains, eat more, and in some way
18 needing better data and better regulation on
19 what a whole grain is.

20 And your point about, you know,
21 how do we set the standard for that, right now
22 it's kind of unregulated. And I guess I

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1 shouldn't - I don't want to get myself in
2 trouble. My impression of regulation is that
3 you can put on grams of whole grain on your
4 product and that's fine. So I think with
5 your Flint study where people are actually
6 measuring grams of whole grain, that is
7 probably where we need to go, and a few grams
8 is really not going to have much positive help
9 with that.

10 I know our Committee struggled,
11 because I think grain fiber is a very
12 consistent strong message, so I think that
13 dietary fiber in food, there is very strong
14 data that we want higher fiber in food, and
15 whole grains are part of that message.

16 DR. CLEMENS: Joanne, Roger.

17 DR. SLAVIN: Yes.

18 DR. CLEMENS: Do you recall any
19 of the studies that included children of
20 teenage years?

21 DR. SLAVIN: For whole grain?

22 DR. CLEMENS: Yes.

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1 DR. SLAVIN: No, there is very
2 little. There are hardly any intervention
3 studies at all. Prospective studies, whole
4 grain, I can't even think of - maybe - I don't
5 think we found anything. I think there is
6 definitely a need for research
7 recommendations. A lot of interest in fiber
8 for kids, whole grain for kids, but very
9 little research has been done in that area
10 that I'm aware of.

11 DR. CLEMENS: I agree, I'm not
12 able to find much either, so thank you for
13 that affirmation.

14 DR. NICKOLS-RICHARDSON: Joanne,
15 this is Shelly. I have a question. In
16 relation to the grain fiber, because I know
17 that the Committee is also looking at other
18 sources of fiber, it's - is there a way that
19 you can connect the grain fiber with other
20 food sources of fiber, and maybe comment on
21 total dietary fiber at this point and how
22 those pieces will fit together? Because I

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1 want to make sure that the consistency among
2 carbohydrate as well as other sources of
3 dietary fiber is consistent from this part to
4 when we look at nutrient inadequacies, so is
5 there a way to connect these pieces yet?

6 DR. SLAVIN: Well, hopefully Eric
7 can help me on this. My sense is that the
8 average person eats mostly grain fiber in the
9 U.S. Intake of fruit fiber and vegetable
10 fiber is very low, and in cohort studies the
11 grain fiber tends to be most protective. But
12 there is this question about it's most of the
13 fiber too. So the strongest data that our
14 Committee finds is grain fiber from cohort
15 epidemiological study. Cheryl, I guess
16 everybody can - but I also think that if you
17 look at the overall dietary fiber and
18 protective cardiovascular disease, that's also
19 strong. It's in the DRI, so there is no
20 question that overall dietary fiber, fiber
21 that is intact, intrinsic, in food, is a
22 positive message, and we want to promote that

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1 message. And that's going to also be in
2 fruits, vegetables, legumes. But our
3 strongest other data for the prospective
4 cohort studies is really for grain fiber.

5 DR. NICKOLS-RICHARDSON: Okay,
6 thank you.

7 DR. ACHTERBERG: This is Cheryl,
8 just to add a little bit more information, I
9 don't recall in the literature any statement
10 that suggests what percent of dietary intake
11 for dietary fiber comes from vegetables and
12 fruits, but I do recall that it's only about 3
13 percent of calories. So when you just
14 consider what form we eat our vegetables and
15 fruit in and then try to figure what fiber
16 contributions might come from that intake,
17 it's really very very low. So I think we need
18 to conclude we don't know what impact
19 vegetable and fruit fibers have yet, because
20 we haven't seen any studies at least in this
21 review where people are consuming enough,
22 Americans are consuming enough, to come up

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1 with a good conclusion.

2 DR. SLAVIN: I think there is
3 some cancer data in other countries where you
4 get higher intakes of fiber. In those data
5 sets, cereal fiber tends to be the most
6 protective.

7 DR. RIMM: This is Eric. I
8 wasn't quite clear on the line of questions.
9 We do get a fair bit of fruit fiber and
10 vegetable fiber in our diets. It's not that
11 cereal fiber is the only source of fiber. I
12 think that most of the cereal fiber is coming
13 from wheat in this country. But I think
14 cereal fiber only represents 30 - 50 percent
15 of all the fiber we get, maybe even less. But
16 there is credible consistent evidence across
17 at least the cardiovascular field that people
18 who have looked at it find most of the
19 benefits coming from cereal fiber, and we
20 hypothesize, well, is it really that
21 different, or is it the fact that most of the
22 cereal fiber is coming from whole grains, and

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1 there is something else about the whole
2 grains? I don't think we know, but it's not
3 that cereal fiber predominates the total fiber
4 intake in this country.

5 DR. SLAVIN: Yes, definitely in
6 cardiovascular disease, cereal fiber is
7 consistently more protective. I know Cheryl
8 is going to talk later on fruits and
9 vegetables and on this discussion. Probably
10 should have brought you in here. Because a
11 lot of fruits and vegetables are really low in
12 fiber, so maybe one to two grams per serving,
13 while a lot of cereal products are actually
14 pretty high in fiber. So there is a dose
15 issue there.

16 DR. WILLIAMS: Joanne, this is
17 Christine. A few years ago I looked at
18 dietary sources of fiber in U.S. children
19 versus children in other countries. And it
20 was interesting that in the U.S. these sources
21 of fiber were about two-thirds from grains,
22 whereas for example like France it was just

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1 the opposite, about two-thirds were from
2 fruits and vegetables. Interesting.

3 DR. SLAVIN: I am sure that is
4 true. In countries where they don't consume
5 whole grains. If you look across countries,
6 you see a lot of whole grains up in the Nordic
7 countries, but France, Spain, you just don't
8 see a lot of that intake. So I would not be
9 surprised at that at all.

10 I do think that overall the
11 dietary fiber recommendation is a really
12 important one, and it's one that is
13 scientifically sound, and a good
14 recommendation, and it will include whole
15 grains, fruits, vegetable, legumes, so you can
16 get your fiber from different sources, but
17 getting it from whole foods is I think a
18 really important method.

19 DR. VAN HORN: All right, are we
20 ready to move on? Any other fiber, whole
21 grain?

22 All right, now we are going to go

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1 into more digestible carbohydrates, and some
2 of the questions we asked for that. Added
3 sugar: so our original question, and remember
4 the kids' comparable question is in energy
5 balance, and you will hear more about that,
6 but in adults, what is the association between
7 the intake of added sugars including sugar-
8 sweetened beverages and energy intake and body
9 weight.

10 So from 2005 DGAC, their question
11 was, what is the significance of added sugar
12 intake to human health? And the conclusion
13 was, compared with individuals who consume
14 small amounts of foods and beverages that are
15 high in added sugar, those who consume large
16 amounts, tend to consume more calories but
17 smaller amounts of micro-nutrients. Although
18 more research is needed, available prospective
19 studies suggest a positive association between
20 the consumption of sugar-sweetened beverages
21 and weight gain. The reduced intake of added
22 sugar, especially sugar-sweetened beverages,

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1 may be helpful in achieving recommended
2 intakes of nutrients and in weight control.

3 So that was their conclusion. For
4 our review, since that wasn't an evidence-
5 based review in the same sense we are doing it
6 now, so it wasn't a NEL review, we decided to
7 go back to 1990 to present. And we included
8 ages 19 and older, childhood overweight
9 section is going to address the sugar-
10 sweetened beverages. The original article
11 included in systematic reviews or meta-
12 analyses were excluded, and cross-sectional
13 studies were excluded. And we tried to give
14 more support to the systematic reviews that
15 excluded cross-sectional studies but it was
16 difficult, because most of them included them.

17 Next slide.

18 In adults what is the association
19 between intake of sugar-sweetened beverages
20 and energy intake. Draft conclusion: little
21 evidence that intake of added sugar including
22 sugar-sweetened beverages is linked to higher

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1 energy intake. Grade II. And in adults what
2 is the association between intake of sugar-
3 sweetened beverages and body weight? Limited
4 evidence from epidemiological studies and RCTs
5 that added sugars, including sugar-sweetened
6 beverages, are more likely to cause obesity
7 than any other source of energy and Grade II.

8 And I wanted to mention as we go
9 on here is that at the beginning of our
10 carbohydrate section, we reviewed overall
11 carbohydrates and energy balance, adiposity,
12 and similar to 2005. And in their review
13 typically carbohydrates are not linked to
14 higher body weight. So you start from this,
15 overall carbohydrate intake if anything is
16 protective against obesity. And then you ask
17 the question, are there differences with
18 different carbohydrates.

19 So energy intake was based on a
20 review of one meta-analysis and three trials.

21 So the meta-analysis the way this was set up,
22 it was soft drink consumption and nutrition

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1 and health outcome. Eight-eight original
2 studies, and some of that data was
3 unpublished. So the data had been gotten from
4 investigators. So in that study it also
5 included cross-sectional studies. So that was
6 the difficulty in trying to put that in a
7 balance with what else was out there that we
8 could find.

9 So the other three studies were
10 different types of studies, and I'll just talk
11 a little bit about them. Very difficult to do
12 these studies, so you can see that there is
13 not a perfect design. But the first one, the
14 Reid study, a parallel arm with four soft
15 drinks added to the daily diet, and then the
16 comparison was regular soft drink versus diet
17 soft drink over four weeks, and they found
18 differences.

19 Now obviously in these types of
20 studies if you get more calories you would
21 expect obviously to get higher energy intake,
22 so not too surprising.

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1 The randomized cross-over trial,
2 the Flood study, with ad lib beverage at
3 lunch. So the differences were regular
4 sweetened cola versus diet cola. And this is
5 a one-day test meal. So they suggested that
6 there was a relationship between sugar-
7 sweetened beverages and energy intake.

8 And then the last study was a
9 crossover trial with a preload followed by
10 test meal. So in these they actually compared
11 different types of beverages. So a sucrose
12 beverage with just regular sucrose, and then a
13 high fructose corn sweetener beverage where
14 they balanced for calories, and then they also
15 compared milk and a diet drink and they saw no
16 differences with those different types of
17 drinks that were calorie balanced.

18 It's very difficult to do these
19 types of studies, depending on what your
20 question was, you can see they are really
21 different the way they were designed. So next
22 slide.

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1 Added sugar and body weight in
2 energy-balance setting. We tried - you can
3 see we went back a long time to get some of
4 these studies that they tried to compare
5 different diets. So the Raben study,
6 crossover case-control with three diets,
7 sucrose-, starch-, fat-rich, in normal weight
8 adults. Sucrose diet, 23 percent of the
9 energy came from sucrose. And then they
10 compared it against these other diets. These
11 are energy controlled diets, so not too
12 surprisingly you don't see differences in body
13 weight. And obviously you only have 14 days,
14 so it would be difficult to find that also.

15 The 2009, this was an interesting
16 study where they compared glucose to fructose
17 at a pretty high energy level over 10 weeks.
18 So on this the parallel arm study so you
19 either got glucose or fructose sweetened
20 beverages. And over 10 weeks was there a
21 relationship between body weight and the
22 energy balance? No, they saw no differences

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1 for body weight, and same amount in both
2 groups and then the last study they compared
3 high and low sucrose weight loss programs.
4 And they went really high. So 43 percent of
5 the energy in sucrose compared with 4 percent
6 in the low sucrose diet, and found no
7 relationship between these different diets and
8 body weight. But remember, these are energy
9 balanced settings. So obviously if you
10 believe calories count, and I think everybody
11 on this Committee does, and you balance
12 calories, you are not going to see any
13 differences whether those calories come from
14 sucrose or starch or however you - fructose
15 versus glucose, that if you balance your
16 calories you will not have any difference in
17 body weight.

18 Next slide. All right, so those
19 are the - you know there are very few studies
20 looking at added sugar per se and body weight,
21 and not much is there. Typically as we
22 started the literature review it is pretty

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1 hard to assess carbohydrates. There hasn't
2 been a lot of effort to assess carbohydrates.

3 I don't think the data is really good. And
4 overall when you look at carbohydrate intake
5 and body weight, carbohydrates across the
6 board are pretty protective.

7 So that data is - if you just ask
8 the question, if people eat more sugar do they
9 weigh more, that data isn't there that they
10 do. But if you go in and ask some of the
11 conclusions - something that you can count
12 fairly well probably in epidemiological
13 studies, which would be, sugar-sweetened
14 beverages, are there relationships to body
15 weight. So if you ask that question, are
16 sugar-sweetened beverages related to body
17 weight, we had three systematic reviews, a
18 meta-analysis, four perspective observational
19 studies, and two trials.

20 So if you look at the systematic
21 reviews, they are really messy. So we put
22 them all up there just so you could compare

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1 them, and you see on the note on the bottom
2 studies that are in blue are actually cross-
3 sectional studies. We were trying to not
4 include cross-sectional studies, but all the
5 systematic reviews that were out there
6 actually in some way included them. So you
7 can also see the people who asked for, who
8 sponsored it, that's over in the right column
9 there, and then in the middle are the authors'
10 conclusions.

11 So the Gibson article, sugar-
12 sweetened beverages are a source of energy,
13 and there is a typo there, but there is little
14 evidence that they are more causing of weight
15 gain than any other source of energy. And
16 that is pretty much what you got from the
17 first set of studies that if you balance
18 energy, whether it comes from sugar or any
19 other calorie source you are going to expect
20 the same amount of body weight.

21 But Malik, this one is a little
22 hard to see because of the way it's set up.

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1 It's different - a very different design. So
2 there is some data, some original data in
3 there, plus some inclusion of four prospective
4 cohorts and three intervention studies. A
5 positive epidemiological and experimental
6 evidence indicates greater consumption of
7 sugar-sweetened beverages is associated with
8 weight gain and obesity.

9 The Ruxton study that was recently
10 - came out, in this one they actually had a
11 fairly detailed description of what was
12 included. So they included fewer studies, and
13 their conclusion is the possibility that
14 considerable intake of sugar-sweetened
15 beverages can contribute to obesity risk
16 cannot be discounted. So they looked at
17 really high intake, there would potentially be
18 a link.

19 And the other study that we have
20 already looked at is this meta-analysis, and
21 they conclude that clear associations between
22 soft drink intake with increase energy intake

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1 and body weight were observed.

2 So overall these were all meta-
3 analysis, systematic reviews, in general the
4 people are saying that if calories are
5 controlled, obviously sugar-sweetened
6 beverages are no different than any other
7 calories. So we need to consider them as
8 calories, and obviously if you have no room
9 for calories then they need to go. They could
10 be extra calories and they could contribute to
11 obesity if they are part of the extra calorie
12 problem. Next slide.

13 Okay, some of the studies that
14 have been done, and I mentioned, some of these
15 you have already seen, but this is the
16 question that is going to affect body weight.

17 So this is the relationship between sugar-
18 sweetened beverages and body weight. So going
19 through some of the studies on the top,
20 prospective studies, the Palmer study, more
21 than one soft drink a day versus less than
22 soft drink a day, it does support a

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1 relationship according to the authors on that
2 one.

3 The Framingham Heart looking at
4 different, less than one versus more drinks
5 over four years, there is an association.

6 The Chen study, the Premier Study,
7 compared sugar-sweetened beverages to other
8 beverages, supports a relationship, yes.

9 And then the Stookey, comparing
10 water to sweetened caloric beverages and at
11 different time points, yes, it does support a
12 relationship.

13 If you look at trials, the 2009
14 this parallel arm over 10 weeks, in the
15 outpatient, and this is a little complicated
16 study, because there are different groups that
17 are looked at, and this has been published in
18 a couple of different places. But looking at
19 - giving beverages with glucose and fructose,
20 there was a relationship with weight gain, and
21 then the Reid study regular versus soft drink,
22 and I can't, under my tab here, so I guess I

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1 have my notes.

2 So overall there is a fairly
3 consistent relationship with soft drinks,
4 sugar-sweetened soft drinks, although the Reid
5 study did find - and this is over four weeks -
6 they saw no differences in a parallel arm
7 trial with soft drinks compared to diet soft
8 drinks.

9 If you think of what is the right
10 design, what is the perfect way to get at
11 this, overall I think if you control calories
12 obviously you are not going to see any
13 differences. If you just add calories you
14 would expect, if you have a study that is long
15 enough, you would potentially see weight gain.

16 Next slide.

17 So implications: measurement of
18 added sugars in studies is inconsistent making
19 study comparisons difficult. It's probably
20 easier to count sugar-sweetened beverages. So
21 if you look at some of the inconsistencies of
22 these studies, carbohydrates assessment tools

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1 are fairly limited. Added sugars is a
2 calculation; there is no way to measure added
3 sugar, so it's a hard thing to really get out
4 of epidemiological studies as opposed to
5 sugar-sweetened beverage people ought to be
6 pretty good at counting how many they can
7 consume, so that data is a little stronger.

8 Different types of carbohydrates,
9 whether it's sucrose, high fructose corn
10 sweeteners, there are no differences in
11 satiety or energy intake if you control
12 calories. So there is no - fructose,
13 sucrose, any of those carbohydrates on a
14 calorie controlled basis aren't going to show
15 differences.

16 And I think overall added sugar is
17 not any different than any other extra calorie
18 for energy intake and body weight. So there
19 is nothing uniquely different that sugar is
20 going to - it's four calories per gram just
21 like starch, so if you control calorie intake
22 there is nothing different about added sugar

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1 than any other calorie. And if you go back to
2 2005, the discretionary calorie, it would fit
3 in that category of calories that could go out
4 of the diet and people need to cut calories.
5 Next slide.

6 Any questions? Does anybody
7 want to ask a question about that before we go
8 down the non-caloric sweetener path here?

9 DR. NICKOLS-RICHARDSON: Yes,
10 this is Shelly, I'm going to ask a couple of
11 questions.

12 DR. SLAVIN: Okay.

13 DR. NICKOLS-RICHARDSON: Can you
14 give us a sense of the total energy intake in
15 the studies that were not energy-balanced? So
16 what were the total energy intakes in those
17 participants who were consuming the extra - or
18 the sugar-sweetened beverages in relationship
19 to what energy needs might have been?

20 What I'm getting at here, I think
21 when we look at, and when we get to this
22 tomorrow, when we look at total energy in the

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1 diet of Americans, and we look at sources of
2 added sugars and how much - a third of
3 calories come from added sugars and solid
4 fats, we know that about 37 percent of the
5 sugar that is added is from sodas in
6 particular. So what I'm getting at is that
7 while these lab-based studies are interesting
8 and that is how we want to conduct our
9 scientific reviews here, but America is not an
10 energy balance. So in this sort of large,
11 broad, population based ecological study that
12 we are undergoing, how relevant are these for
13 energy balanced studies? So what is the
14 energy intake in these non-energy balanced
15 studies in relation to energy needs and how do
16 these sugar-sweetened beverages fit in?
17 Because I'm a little concerned about - and
18 maybe it's the wording of the questions and
19 the conclusions - but I'm a little concerned
20 to just leave it at sugar-sweetened beverages
21 don't come at a cost to the American
22 population.

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1 DR. SLAVIN: Maybe Eric can help
2 me too on these. I think you can count sugar-
3 sweetened beverages pretty well, but I don't
4 know in a cohort study how you are going to
5 get at added sugars as a number. And you have
6 to remember that in these studies that overall
7 carbohydrates across the board are pretty
8 protective.

9 DR. NICKOLS-RICHARDSON: Sure.

10 DR. RIMM: This is Eric. I think
11 Shelly's point is an excellent one. The
12 question is, if you hold calories constant,
13 then it can come from soda or come from other
14 things. In the free living population, is it
15 true that people who consume sugar-sweetened
16 beverages end up consuming more calories.

17 DR. SLAVIN: I don't know --

18 DR. RIMM: That's why I think in
19 this case some of the prospective studies may
20 shine some light on it, because we do measure
21 soda consumption pretty well because it is
22 such a unique distinctive food in portion

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1 size. It may be more challenge to measure
2 protein because it is in so many different
3 foods in small amounts. But when people
4 report their sugar-sweetened beverages or diet
5 beverages it's pretty accurately reported.

6 DR. SLAVIN: And you know we may
7 need to have this discussion after the next
8 section, because the data on non-caloric is
9 not totally going to help us out if we say,
10 okay, if we get rid of sugar-sweetened
11 beverages and go to non-caloric there is going
12 to be a net gain. We don't have great data on
13 that. Unfortunately. And as I mentioned, I
14 don't think our carbohydrate assessments tools
15 are that good. So you know I completely agree
16 with you, Shelly, I personally think that
17 sugar-sweetened beverages, obviously there
18 aren't lots of other nutrient densities that
19 go along with them, so it's something that
20 could be excluded, but we wouldn't want
21 someone to turn around and then take in fruit
22 juice or energy drinks to think that somehow

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1 that would be better or starch, you know like
2 cookies or something. So by focusing on added
3 sugar we need to really focus on calories, so
4 we don't want to get away from the calorie
5 message.

6 DR. APPEL: Hi, this is Larry.
7 The one study that I'm more familiar with than
8 the others is PREMIER, because I was a co-
9 author on that, and it does address Shelly's
10 question, actually provides calories, both for
11 liquid calories and sugar-sweetened beverages.

12 There is also one point, because it's not
13 just a cohort study, it's really - it's a
14 study of changes in intake in a clinical trial
15 so it's probably the closest thing to a long
16 term trial. The thing that wasn't mentioned
17 that I think is very important is that there
18 was a direct dose-response relationship
19 between weight change and change in sugar
20 sweetened beverage, so the more people reduce
21 their sugar-sweetened beverage intake the more
22 weight they lost. The way the table is

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1 phrased it's sort of a comparison of sugar-
2 sweetened beverage versus other beverages, but
3 that is not the primary analysis. It really
4 was the one I just mentioned; it was a clear
5 direct dose-response relationship, and that
6 was presents at six months and at 18 months.
7 So both for weight loss and weight
8 maintenance.

9 DR. VAN HORN: Great. Good
10 points. Other people? Any other comments?
11 How are you holding up, Joanne?

12 DR. SLAVIN: Good. I think that
13 once we go through maybe the next section we
14 can have some other questions, and try to
15 bring those together. All right, next slide,
16 added sugars. Next slide. Non-caloric
17 sweeteners. How are non-caloric sweeteners,
18 related to energy intake and body weight?
19 This one is a little different in that the ADA
20 did an evidence - their Evidence Analysis
21 Library completed a review of non-nutritive
22 sweeteners for children and adults in 2006.

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1 And the NEL search really provided an update
2 for this review. Next slide.

3 Our draft conclusion: this is
4 obviously the same calorie issue. If non-
5 caloric sweeteners are substituted for higher
6 calorie foods or beverages, they are
7 associated with weight loss. Observational
8 studies find that individuals who use non-
9 caloric sweeteners are more likely to gain
10 weight or be heavier. This does not support
11 that non-caloric sweeteners cause weight gain;
12 only that they are more likely to be used in
13 overweight and obese individuals. This is a
14 Grade II. Next slide.

15 Some of the ADA EAL conclusions.
16 First in adults, using non-nutritive
17 sweeteners in either a calorie-restricted or
18 ad lib diet will affect the overall energy
19 balance only if non-nutritive sweeteners are
20 substituted for higher calorie food and
21 beverages, Grade II.

22 And then children and adolescents,

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1 studies do not support the use of non-
2 nutritive sweeteners that they cause weight
3 gain. If non-caloric beverages, including
4 non-nutritive sweeteners, are substituted for
5 sugar-sweetened beverages there is a potential
6 for energy savings in adolescents, Grade III.

7 The NEL update identifies three
8 additional articles that we looked at. The
9 meta-analysis, 2006, body weight as an
10 outcome. Significant reduction in weight with
11 intake of aspartame. Energy intake over 24
12 hours as an outcome. Significant reduction in
13 energy intake when aspartame was compared with
14 all types of controls except non-sucrose
15 controls such as water.

16 The one randomized trial
17 participants consumed significantly more
18 energy at a meal when cola was provided versus
19 diet cola or water.

20 And then the prospective study,
21 significant positive dose-response
22 relationship between artificially sweetened

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1 beverage consumption and incidence of over
2 weight and obesity. The point - it's pointed
3 out that this association does not establish
4 causality.

5 Non-caloric sweeteners,
6 implications. Obviously if you take sugar out
7 with calories and you are replacing it with
8 sugar free, you should theoretically reduce
9 body weight. There are many questions that
10 remain because epidemiological studies
11 typically will find a positive link with use
12 of non-nutritive sweeteners and BMI. While
13 animal studies which we have not used in our
14 reviews suggest that the inclusion of non-
15 nutritive sweeteners in the diet promotes
16 energy intake and contributes to obesity. So
17 there is a concern in some people, in animal
18 studies, that non-nutritive sweeteners, if you
19 allow animals in some of these studies they
20 will actually consume more calories, and that
21 is something - a concern that people make up
22 those calories in other ways.

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1 Typically non-nutritive sweeteners
2 are not used randomly across the population.
3 They tend to be more female, women who are
4 dieting, people that are already overweight.
5 So epidemiological studies are somewhat
6 limited because of that, so that if you try to
7 do a fair question here it would be difficult
8 to do. I think long term randomized control
9 will be required to resolve whether non-
10 nutritive sweeteners can actually aid weight
11 loss or prevent weight gain. We really don't
12 have - some of the studies we saw early on and
13 there is an overlap with the added sugar
14 chapter, some of the studies we found where
15 you compare a diet soft drink to a soft drink
16 in these types of short term weight loss
17 studies, there are really not many of those
18 studies that show, theoretically, yes, if you
19 cut calories you should have an effect on body
20 weight. But you don't have large scale
21 randomized trials that show that, the type of
22 data we would really like to have. We just

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1 don't have that.

2 So any questions about
3 artificially sweetened beverages or added
4 sugar before we go on?

5 DR. APPEL: Yes, this is Larry.
6 I have a little bit of concern when you
7 mentioned a randomized trial needed, because I
8 actually think these -- I mean I try to do
9 these studies, and this might be one area
10 where you can't actually do a randomized
11 controlled trial. I'd have to really think
12 through - there have been a lot of issues
13 dealing with sugar-sweetened beverages I don't
14 think lend themselves easily to trials, and I
15 don't want to leave the impression in the
16 Report that we are waiting for something to be
17 done or that might be done but is unlikely to
18 be done if it's done, might not be done well.

19 DR. SLAVIN: Well, I agree with
20 you that it would be a hard study, people
21 would say, okay, it's easy if you put - move
22 all the sugar-sweetened beverages to diet

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1 without even telling people, and how much
2 weight, according to this calculation, you
3 should lose this much weight, I think those
4 would be very difficult studies to do.

5 DR. APPEL: Or you do a two-armed
6 study and one person gets the sugar - I mean
7 the non-nutritive sweetener, and the other
8 person gets a sugar-sweetened beverage and you
9 don't know whether it's the reduction in
10 sugar-sweetened beverage or the non-core
11 sweetener that was substituted. I actually
12 think you should retract that piece from that
13 implication, or just modify it because it
14 implies - we should be doing trials.

15 DR. SLAVIN: I think if you go
16 into the non-caloric sweetener literature
17 there is a ton of data on safety; there are
18 really a lot of animal studies out there. But
19 I think the public is kind of wanting, if I
20 switch to an artificial sweetener I'm going to
21 lose weight, well, yes, you probably are right
22 it would probably not be possible to even have

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1 that kind of data, and we don't have that
2 data that says, yes, if you switch, if you are
3 going to switch over to non-caloric you are
4 going to loose weight. Theoretically you
5 should. If all other calories are the same
6 and you cut out 100 calories a day
7 theoretically you should lose weight, and
8 maybe that's the way to leave it, that the
9 likelihood of having a controlled trial to
10 prove - and there really is - because of the
11 animal data there is a lot of concern that
12 people actually eat more, like they somehow,
13 because they are not gaining digestible
14 carbohydrates they pick up more calories
15 throughout the day in other ways, and that is
16 only animal data that I have seen on that, not
17 human data.

18 DR. RIMM: Larry, this is Eric,
19 but don't you think you could do a trial where
20 you had three arms where it was water, non-
21 nutritive sweetener, and sugar-sweetened
22 beverage just to see if there was - some

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1 people say it's a training of the palette that
2 you have Nutrasweet or non-nutritive sweetener
3 that you are training the palette to still
4 like very sweet foods, so it is driving you to
5 eat more energy during the day. But if you
6 replace it with water you could have a
7 meaningful comparison.

8 DR. APPEL: Yes, I think it also
9 gets to some of the complexities related to
10 the total amount of calories from these
11 beverages. Because you'd have to start off
12 with a baseline of very high consumption, or
13 at least make that one of the arms be that, so
14 that the sugar sweetened beverages would be
15 four drinks or five drinks a day or something
16 like this for the contrast. I tried to think
17 about these studies and I'm sure others have,
18 I just - you are going to have a tough time
19 doing this.

20 DR. RIMM: You don't think you
21 could do a two-year trial like the POUNDS LOST
22 study where it was just three arms? You could

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1 see a weight difference over two years? I
2 mean you are right, it's a really difficult
3 study, but I think by comparing - I don't
4 think we should throw it away completely,
5 because there is this issue where there is the
6 data from animal studies suggesting that if
7 you give them non-nutritive sweeteners that
8 they tend to want sweeter food even though
9 there is no calories in that food per se. So
10 I don't know if -

11 (Simultaneous voices)

12 DR. RIMM: -- the hypothesis, so
13 if you had three arms you could test that.

14 DR. APPEL: I guess what I would
15 - that we are not - I wouldn't end the
16 conclusion with the long term problem. So
17 unless we really thought that these could be
18 easily done. I still think there are big
19 logistic issues in doing this, and - but I
20 just don't want to see an implication that
21 ends with a trial where we are not really the
22 best employed, best designed, best of proposed

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1 trial.

2 DR. FUKAGAWA: This is Naomi. I
3 support sort of you, Larry, in terms of not
4 having that recommendation or implication
5 also, because in many ways what we are trying
6 to get at is the whole issue of whole diets
7 and whole foods, and in a sense going down the
8 path of non-caloric sweeteners takes us away
9 from what we really are trying to do, namely,
10 alter or have an impact on choices that people
11 make, not as substitutes for reducing
12 calories. Does that make sense?

13 DR. NELSON: This is Mim. I just
14 joined, sorry for having to teach this
15 morning. But I also don't think in the
16 implication that we have been really putting
17 sort of research directions in the
18 implications. I think I agree; I think it
19 could be elsewhere but it doesn't need to be
20 here.

21 DR. SLAVIN: That is not a
22 problem. I think that probably was in the

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1 research section and got added. So it
2 definitely doesn't fit under that.

3 DR. FUKAGAWA: Because maybe one
4 of our broader questions is, do we really need
5 non-caloric sweeteners in the food supply.
6 Just a question.

7 DR. NELSON: I would say no.

8 DR. SLAVIN: But I do think
9 giving people tools, as we know they are going
10 to need to eat fewer calories, are those tools
11 successful to help people, and theoretically
12 they should help people.

13 DR. FUKAGAWA: I guess if you
14 phrase it in that manner, as tools to get from
15 one end to the other, but not the answer to
16 how we might be able to maintain energy
17 balance.

18 DR. NELSON: Yes, the place where
19 this gets real sticky I think is when you
20 consider children, and the fact is the data
21 show that consumption of sugar-sweetened
22 beverages in children does not influence their

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1 reduced intake of calories later, which we
2 kind of had thought was a possibility in fact
3 we haven't seen that. Therefore, the
4 temptation to provide non-caloric sweetened
5 beverages for children so that they can drink
6 something besides water and not add
7 unnecessary calories becomes a real target of
8 question. So I think while data and research
9 on the subject of whether non-caloric
10 sweeteners actually contribute to weight gain
11 certainly would have a major impact on that
12 sub-group within our population, perhaps,
13 again we just don't have the data right now to
14 give us any guidance on that. So the training
15 of the palette issue I think does become an
16 important one especially when it comes to
17 children, because long term adaptations to a
18 non-caloric sugar - not sugar-sweetened
19 beverage could have major implications for
20 them in terms of their cravings for higher
21 sugar flavored food. I don't think we can
22 resolve it here.

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1 DR. SLAVIN: Well, we will
2 definitely take it out of implications, and
3 come up with some research recommendations.
4 But I would love to get to solids versus
5 liquids, because there is a lot of overlap in
6 all these categories, and I have a little note
7 here that I am a little behind.

8 So liquids versus solids, what is
9 the impact of liquids versus solid foods on
10 energy intake and body weight, a question from
11 the 2005 DGAC. What is the evidence to
12 support caloric compensation for liquids
13 versus solid foods? An unresolved issue: the
14 evidence is conflicting that liquid and solid
15 foods differ in their effect on calorie
16 compensation.

17 For our review we went back to
18 2000 to present, and only included articles
19 that compare a liquid to a solid or semi-solid
20 form. We only included articles that
21 considered energy intake and/or body weight
22 not appetite or hunger. This was a very

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1 difficult review.

2 And here is our draft conclusion.
3 When calorie consumption of preloads is
4 balanced, in these studies, a lot of these
5 studies are done with preloads, there are few
6 differences in energy intake between liquid
7 versus solid treatments. So if you actually
8 control calories at your preload and figure
9 out how much somebody would eat at lunch, is
10 kind of a typical design, calories are
11 controlled at the beginning, you don't see
12 differences. Reduction in liquid calorie
13 intake had a stronger effect on weight loss
14 than did a reduction in solid calorie intake
15 in the PREMIER study, but the difference was
16 statistically significant at six months, not
17 18 months. I appreciate Larry's comments on
18 this and how they fit in here. On an energy-
19 restricted diet soup consumption is associated
20 with 50 percent or greater weight loss. You
21 can see our conclusions are really all over
22 the place, and part of this is because the

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1 designs are really different in this area. So
2 here are the studies. I'm not going to spend
3 a lot of time on this, but if you will look
4 the PREMIER study they separated liquid
5 calories and dissolved calories and saw
6 differences. If you go down, you have already
7 heard about some of the - like the jelly bean
8 study where they compared - they compared pop
9 versus jelly beans. They saw some differences
10 with liquids versus solids. But if you go
11 down some of the - like the Mattes study that
12 was recently published looking at different
13 food forms, no differences with food form and
14 daily energy intake. Same thing with the
15 Flood, looking at that one. There were
16 differences between apples and apple juice,
17 but if you put - added fiber into the apple
18 juice that didn't really affect food intake.
19 It wasn't just the fiber. The 2004 crossover
20 trial with preload followed by the ad lib
21 lunch, no differences depending on food forms.

22 So in general food form in these

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1 studies, inconsistent results. And you see
2 the different colors on the bottom: these are
3 the soup studies. The soup studies are done
4 differently. There is a concept that perhaps
5 the temperature of something affects food
6 intake; having the forms - there are typically
7 a lot of foods have solids within a liquid, a
8 lot of times people having soup before a meal
9 they eat less later. So these are very
10 different study designs. And overall you see
11 some effect of soup consumption actually as a
12 liquid decreasing calorie intake. So that
13 kind of confounds this whole concept of people
14 thinking that liquid calories don't work as
15 well as solid calories or number of calories
16 that people take in.

17 Our next slide: so some of the
18 implications. Macronutrients of a liquid diet
19 and a solid diet are the same. There is
20 little data - there are little data that food
21 form affects energy intake in those types of
22 studies. Food structure does seem to play

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1 some role in food intake. So whole foods may
2 affect satiety; there is a little bit of data
3 on that. And people may eat less at a
4 subsequent meal when they eat a whole food.
5 And also soup liquid calories as far as soup
6 seems to be an aid for weight loss. So the
7 soup data doesn't quite fit in with some of
8 the other data for unknown reasons. Okay,
9 next slide. Any questions on food form?
10 Really hard topic. Really appreciate all the
11 help in trying to find the data. That is
12 another thing that typically cohort studies
13 don't pick up food form, but that is something
14 people ask about, or even how many beverages
15 do people drink, how much water do people
16 drink in a given day.

17 All right, satiety. This was a
18 non-NEL review. And because it's huge, and
19 we were kind of - ran out of time basically.
20 And so it wasn't NEL, but the draft
21 conclusion: many factors affect satiety, and
22 most studies are conducted in laboratory

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1 settings to control for variables. Therefore
2 these results may not be generalized for more
3 complicated eating environment in the outside
4 world.

5 In general foods high in fiber are
6 generally more satiating than low fiber foods,
7 although you just heard about this study when
8 fibers are added to drinks, that a lot of
9 times that doesn't affect satiety. In general
10 small changes in macronutrients are probably
11 not going to have large differences in
12 satiety. If you get into all the
13 macronutrient proteins, fats - carbohydrates
14 in the reviews that have been done, you get
15 mixed messages. Probably protein comes up the
16 most likely, but it's not consistent. Next
17 slide. And then our last - or
18 this question was the role of prebiotics and
19 probiotics in health. And this was really
20 based on a lot of the public questions we go.
21 We wanted to make sure we addressed this. We
22 also used a non-NEL review of this literature.

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1 And our conclusion, and I guess I'm speaking
2 for our Committee here, but we believe that
3 the gutmicrobiota does play a role in health
4 although the research in this area is still
5 developing. No recommendations for intake of
6 prebiotics or probiotics for the American
7 public can be made, although foods high in
8 prebiotics - wheat, onions and garlic - should
9 be consumed as well as food concentrated in
10 probiotic, such as yogurt. Next slide.

11 Cheryl, any questions for me? I'm
12 going to give the last time that we have here
13 to Cheryl, because in the November public
14 meeting we still had fruit and vegetable data
15 that didn't get presented. So any questions
16 on added sugar or liquids, anything, before I
17 turn this over to Cheryl.

18 DR. PEREZ-ESCAMILLA: Joan, this
19 is Rafael Perez-Escamilla.

20 DR. SLAVIN: Yes.

21 DR. PEREZ-ESCAMILLA:: It seems
22 to me that your conclusions on satiety and

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1 fiber are fairly consistent with the energy
2 density weight loss conclusions that we
3 reached in the energy balance of the
4 Committee. So I was wondering if you agree
5 with that, because I think it is important for
6 the integration chapters to integrate these
7 two questions.

8 DR. SLAVIN: No, I think as we go
9 - you can see a lot of the topics that we have
10 in this subcommittee overlap big time with
11 energy balance, so as we get to that
12 discussion any time there are any
13 inconsistencies we definitely want to have
14 that pointed out. But I don't think I see one
15 for the satiety.

16 DR. PEREZ-ESCAMILLA: I agree;
17 thank you.

18 DR. APPEL: It's Larry again. I
19 wanted to go to your conclusion and the
20 implications for added sugar. And I'm
21 wondering whether you need to pull out the
22 sugar-sweetened beverage and weight. I'm

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1 looking at the slides that you show on the
2 three systematic reviews and the meta-
3 analysis, and also the studies of - since
4 then, the next slide. And it seems to me that
5 the evidence is stronger than a Grade II and
6 worthy of pulling it out from the added sugar.

7
8 DR. SLAVIN: All right, I'm on -
9 let's see - well, when we - we did split it up
10 because we thought okay the data on sugar-
11 sweetened beverages is - it seems like there
12 is more data, a little more consistent, so we
13 did split it out.

14 DR. APPEL: The conclusion,
15 though, on this slide, the question is related
16 to sugar-sweetened beverages and body weight,
17 and the draft conclusion starts out with added
18 sugar, which I agree with you are more
19 difficult to measure. But your data that you
20 present in the subsequent slide on sugar-
21 sweetened beverages looks to me to be pretty -
22 pretty consistent with one exception being the

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1 largest systematic review but it also included
2 all the cross-sectional studies.

3 DR. NICKOLS-RICHARDSON: This is
4 Shelly, and I agree with that, and I think
5 maybe it's limited evidence, but it's pretty
6 strong and consistent, so I think that is the
7 discrepancy that I see is the little evidence
8 that doesn't quite - there is just something a
9 little bit missing there for me.

10 DR. APPEL: I think I'd be
11 interested in hear what Xav said, because he
12 was tortured a few years ago on this question.

13 But part of the problem was that people were
14 stuck with sort of crappy evidence, these
15 cross-sectional studies. And there is better
16 evidence now, and it's been reviewed and been
17 done in a systematic way, especially for some
18 of the prospective studies and now some trial
19 or secondary analysis at trial. It's a
20 stronger body of evidence, and it doesn't come
21 across right now in the conclusion.

22 DR. SLAVIN: I guess, too, Larry,

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1 what I didn't present here was the whole
2 overall - the carbohydrates and body weight.
3 I think in the research section we are really
4 going to have to come up with better
5 measurement tools. And carbohydrates are
6 linked to more body weight, so that is where
7 we start with this data. So the nice thing
8 about sugar-sweetened beverages is, typically,
9 you can count those. So you usually get a
10 little more information but if you look at the
11 systematic reviews, they are pretty
12 inconsistent depending on how people go after
13 it. And I think the question is, does it
14 really matter who sponsored them or whether
15 you take in the cross-sectional. And if you
16 take out the cross-sectional then you really
17 don't have - it's much weaker. Xav is here,
18 so I would love for - we are more than - our
19 Committee would be happy to reconsider the
20 grade. I don't think it's a Grade I, though.

21 DR. APPEL: No, I agree it's not
22 a Grade I. But I think the phrasing of it,

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1 limited evidence, I think part of the problem
2 is that the evidence previously was not
3 particularly robust evidence, so if you look
4 at more of the prospective studies, it's
5 stronger. But --

6 DR. VAN HORN: Growing evidence,
7 or limited? But increasing evidence?

8 DR. SLAVIN: Yeah.

9 DR. NICKOLS-RICHARDSON: This is
10 Shelly, I agree, too, I'm not saying that the
11 grade should necessarily be changed, but I
12 think there should - there is something
13 missing between either how the question is
14 phrased and the conclusion is phrased and then
15 the evidence, the modifier that precedes the
16 evidence statement, so there is just - I don't
17 have a problem with the grade, because the
18 data are what they are, but it's the phrasing
19 of that limited and little --

20 DR. APPEL: You might have - and
21 I don't think we are here to wordsmith, you
22 might just say, although previous evidence

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1 which is predominantly cross-sectional
2 studies, was inconclusive, more robust
3 evidence from prospective studies supports the
4 relationship between sugar-sweetened beverage
5 intake and weight.

6 DR. SLAVIN: And I was wondering
7 if in the energy intake section, is Christine
8 on, are we going to be - because I know that
9 we have summarized a lot of this data from a
10 kid and an adult site. We probably need to
11 bring that together and make sure we are
12 consistent on that.

13 DR. NICKOLS-RICHARDSON: This is
14 Shelly, and I'm not disputing the whole
15 overall carbohydrate conclusion. But because
16 this has been separated out from overall total
17 carbohydrate, I don't think it should be lost
18 within total carbohydrate. It needs to stand
19 alone as sugar-sweetened beverages, and not
20 even added sugars per se, but sugar-sweetened
21 beverages.

22 DR. SLAVIN: I'm wondering, Eric,

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1 if you are here, is there anything - can you
2 think of a cohort sitting there, are there any
3 studies that need to be pulled out as strong
4 new evidence that doesn't kind of get washed
5 out in these systematic reviews?

6 DR. RIMM: I think there have
7 been. Again I know more about the ones that
8 we have done here than the totality of
9 evidence. The Malik study which you talked
10 about where she looked at our data here and
11 then did a sort of meta-analysis at the end, I
12 thought there was something - maybe it was
13 sugar-sweetened beverage and diabetes also
14 where there was analysis that really changed
15 in sugar-sweetened beverage, showing that
16 people who increased their intake
17 prospectively had an increased risk of
18 diabetes, so it wasn't just cross-sectional,
19 and it wasn't just one point in time
20 prospectively; it was actually two points in
21 time. So I - it is a really hard thing to
22 measure, and you can really dilute messages by

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1 looking at things that were not done with the
2 best methods available. It's not that they
3 were incorrect; it's sort of all the data that
4 they had. So it is tough to weight, but I
5 think trying to - looking at those studies, I
6 look at change over time may be the best way
7 to do it. I have to go back and look at the
8 Malik study, but I thought that's what she
9 did.

10 DR. APPEL: This is Larry again.

11 I think that you are right on target, Eric,
12 sort of like the one way - or just sort of the
13 cross-sectional cut or the prediction without
14 looking at change, that is not done in most of
15 the cohort studies.

16 DR. SLAVIN: I really think that
17 what happens in these meta-analyses is that we
18 lose our signal, it washes out. So if we had
19 some good prospective studies or other ways of
20 looking at this to make sure that that doesn't
21 get lost, we should definitely include that
22 and bring that kind of to the front of the

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1 line. Because I think everybody here kind of
2 has an agenda. So trying to sort the
3 prospective - these meta-analyses out is very
4 difficult.

5 DR. VAN HORN: Exactly. And this
6 is Linda again, as we have said before, and
7 this I know will come up again in reading the
8 chapters, this is a constantly recurring
9 problem in how you phrase something that is
10 based on a grade that incorporates certain
11 types of studies that may be more robust than
12 others, even though there is a grade attached.
13 And interpreting that really does become
14 problematic. But I think we need to move
15 ahead. Are there any other statements for
16 Joanne?

17 DR. SLAVIN: Right, and Cheryl
18 has her part.

19 DR. VAN HORN: Oh, Cheryl, that's
20 right.

21 DR. SLAVIN: So I will defer to
22 Cheryl. I'm sorry to take all your time.

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1 DR. ACHTERBERG: I will go
2 quickly.

3 I first want to commend Joanne for
4 yeoman's task, not only presenting today but
5 for all the work she's done, a huge amount of
6 questions and papers and data to sort through
7 for this chapter.

8 My mission today is to wrap up a
9 small piece that was not presented in November
10 relative to the effect of vegetables and fruit
11 on health outcome, and more specifically on
12 type 2 diabetes. The question was: what is
13 the relationship between the intake of
14 vegetables and fruits, not including juice, on
15 type 2 diabetes. For the review strategy the
16 topic was addressed in 2005, by the Dietary
17 Guideline Committee, so their conclusions
18 informed this Committee. But in addition we
19 did a literature review using the NEL process
20 from 2004 to 2009, focusing solely on adults.

21
22 There were a total of five

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1 studies. Our draft conclusion is that the
2 evidence is inconsistent, but suggests an
3 inverse association between the development of
4 type 2 diabetes and total vegetable and fruit
5 consumption with a Grade III. All five
6 studies were prospective and long term, a
7 couple of them actually lasted over an 18 or
8 20-year period. Two of the five focused on
9 only specific foods, the Halton on potatoes
10 and more specifically French fries, and the
11 Wang study was solely in this paper on tomato-
12 based products.

13 Altogether with the other three
14 studies, not focused on potatoes or tomatoes,
15 the number of fruit and vegetable servings
16 range from 2-1/2 to more than 10 servings per
17 day. So if you look at the outcomes for
18 these, it's basically a null outcome in the
19 Bazzano study, the Nurses' Health Study as
20 well as the Women's Health Study. A null
21 outcome for the tomato-based products. A
22 positive outcome and association between

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1 intake of potatoes and French fries with the
2 results being stronger for French fries than
3 potatoes in general with type 2 diabetes, and
4 that effect was stronger in obese women than
5 in non-obese women.

6 And then finally if you look at
7 Villegas, this study was conducted in China
8 and did break down vegetables into different
9 categories. It was the only one that did so
10 here. So you can see the inverse relationship
11 for vegetables but not for fruit when you look
12 at these various subgroups.

13 So no information on children and
14 overall we think this supports that draft
15 conclusion that follows, that the evidence
16 thus far is inconsistent. But the Committee
17 believes there is an inverse association
18 probably present between consumption of
19 vegetables and fruits and type 2 diabetes.

20 So that opens us up into the
21 larger fuller discussion if we want to
22 dedicate any more time.

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1 DR. PEREZ-ESCAMILLA: Cheryl, this
2 is Rafael Perez-Escamilla. The intake of
3 vegetables in the U.S. is so low, and the
4 variety also so limited, that this is an area
5 perhaps studies from countries outside the
6 U.S. where there is a much higher intake of
7 vegetables, much more variety, and a wider
8 range, maybe better suited to determining the
9 relationships between the vegetable intake and
10 type 2 diabetes.

11 DR. ACHTERBERG: In my drafting
12 of the chapter here focusing on vegetables and
13 fruits, there is considerable discussion given
14 to the difficulty in these studies and in the
15 comparison across studies given the fact that
16 as you are looking at different countries, the
17 kinds of vegetables and fruits as well as the
18 amount of vegetables and fruit consumed vary
19 quite a bit. And since there are very few
20 hypotheses or mechanisms suggesting for how it
21 impacts my work whether it's about diabetes or
22 cardiovascular disease or other health

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1 outcomes it gets very tricky when any given
2 vegetable for example might contain 400, 500,
3 600 different compounds. So one cannot
4 presume that these results would be constant
5 across nations here, given the different
6 dietary patterns, not only with fruit and
7 vegetables themselves but also in the context
8 of the whole diet. So I would suggest that we
9 need a lot of further research in this area,
10 and a much more rigorous research conducted in
11 terms of data collection on vegetable and
12 fruit intake.

13 DR. RIMM: This is Eric. I mean
14 I wonder it starts and points you to sort of
15 the differences between the fruits and
16 vegetables, just in their impact on diabetes.

17 You could say that the potatoes were positive
18 and some of the other fruits and vegetables
19 are negative. And I know that potatoes in the
20 past have systematically been put into the
21 vegetable category. But clearly the amount of
22 starch and free starch, free glucose, that

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1 comes from potatoes and French fries is much
2 greater than what you'd see from other fruits
3 and vegetables.

4 DR. ACHTERBERG: Correct.

5 DR. RIMM: I don't know, I guess
6 there aren't enough studies out there yet that
7 have looked specifically at potatoes for other
8 outcomes or for diabetes, but it does point to
9 the glycemic quality of the fruit or
10 vegetable.

11 DR. ACHTERBERG: In our NEL
12 search there was only the one study on
13 potatoes. And as you know probably tomorrow
14 we will talk about the modeling that was done
15 so in part we wanted to model what would
16 happen if we looked at these starchy
17 vegetables from a different perspective. So I
18 think you are right, we need to look at
19 vegetables, starchy vegetables and others as
20 well in a more nuanced way than we have in the
21 past, not just lumping them all together.

22 DR. CLEMENS: This is Roger.

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1 Thank you for that excellent insight. It
2 would interesting to raise the issue on starch
3 vegetables that we be careful how we define
4 what a starchy vegetable might be, at what
5 point do we want to look at insulin response
6 or digestibility or actual composition of
7 those types of products.

8 DR. ACHTERBERG: I grant you, and
9 I think especially because of our time
10 pressure here, I defer to the discussion that
11 will arise tomorrow when more of this modeling
12 has been done, and we can present those
13 recommendations.

14 DR. CLEMENS: Thanks, Cheryl.

15 DR. VAN HORN: Other comments
16 from anyone on the panel? Or Joanne or
17 Cheryl, do you have more to add?

18 All right, then, well, it's been
19 an incredible and very comprehensive start
20 today. But I think now our group will take a
21 15-minute break, and please return by 11:45
22 Eastern time, and we will proceed with the

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1 fatty acid report.

2 Thank you.

3 (Whereupon at 11:35 a.m. the
4 proceeding in the above-entitled matter went
5 off the record to return on the record at
6 11:49 a.m.)

7 DR. VAN HORN: All right, well
8 welcome back everyone. We are about to
9 proceed with the fatty acid cholesterol
10 subcommittee. And the chair of that Committee
11 is Dr. Tom Pearson how is going to lead us
12 through the next set of slides.

13 FATTY ACIDS AND CHOLESTEROL SUBCOMMITTEE

14 DR. THOMAS PEARSON: Well, thank
15 you, Linda, and it's a pleasure to begin this
16 report on behalf of our Fatty Acids and
17 Cholesterol Subcommittee. And I want to thank
18 the members. We are going to be hearing from
19 Eric and Roger as well as I will mention in a
20 moment, I think we want to thank and really a
21 great note of appreciation to our staff who
22 have been really so terrific, Shirley Blakely,

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1 Thomas Fungwe, Patricia Guenther and Molly
2 McGrane. So this is the end of a lot of
3 discussions on these important topics. Next
4 slide.

5 What we are going to do is finish
6 up some of the topics that we hadn't fully
7 done in previous sessions. The first question
8 is: What is the influence of dietary fat on
9 cardiovascular disease and other health
10 outcomes? I am going to be covering the first
11 two topics, that is, monounsaturated fatty
12 acids and n-6 Polyunsaturated Fatty Acids.

13 That will be followed by Eric Rimm
14 who is going to look at n-3 Polyunsaturated
15 Fat, particularly in seafood and seafood-
16 derived n-3s versus plant-derived n-3s.

17 And then Roger Clemens is going to
18 talk about maternal intake of seafood and
19 breast milk composition and health, a new
20 topic for the advisory guidelines fatty acid
21 group.

22 Then I'll be back talking about

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1 the association between the consumption of fat
2 of particular foods that are high in fats and
3 their relationship to health outcomes. And
4 the two I'm going to talk about is nuts and
5 chocolate.

6 And then we have the final
7 question of what dietary components of the
8 trans-fatty acids, natural versus synthetic,
9 affect plasma LDL, HDL, and non-HDL
10 cholesterol? And then finally report on three
11 food pattern modeling exercises. In terms of
12 cholesterol-raising fat is, what is the impact
13 on food choices and overall nutrient adequacy
14 of limiting cholesterol raising fatty acids to
15 less than 7 percent of total calories and less
16 than 5 percent of total calories.

17 And the second one that I will be
18 presenting is: what is the impact on food
19 choices and overall nutrient adequacy of
20 limiting dietary cholesterol to less than 200
21 milligrams per day?

22 And then Eric will be back looking

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1 at the modeling question of what is the impact
2 on nutrient adequacy of increasing seafood in
3 the USDA food patterns. So this will be what
4 we will be covering in the next hour and a
5 half or so.

6 So in terms of the monounsaturated
7 fatty acids, we've expanded this into two
8 questions, particularly individuals with type
9 2 diabetes. So the first question: what is
10 the effect of dietary intake of MUFA when
11 substituted for saturated fat on increase risk
12 of cardiovascular diseased in type 2 diabetes
13 mellitus, including intermediate health
14 outcomes such as lipid/lipoprotein levels,
15 markers of inflammation and a blood pressure
16 in the general population.

17 And then the second particularly
18 focused on what is the effect of replacing a
19 high carbohydrate diet with a high MUFA diet
20 in type 2 diabetics? We felt that this was an
21 important subset of the population, not just
22 because diabetes is now affecting about 7

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1 percent of the U.S. population; another 25
2 percent or so have metabolic syndrome which of
3 course is the extremely high levels for
4 developing diabetes.

5 The data looking at these
6 qualities of fat has to do with the isocaloric
7 dietary substitutions. And most of the
8 literature that we have been looking at has
9 been isocaloric in nature, so that you're
10 substituting calorie for calories, and you can
11 see this reviewed by Frank Hu in 2001 the
12 various substitutions, saturated fat for
13 carbohydrates, monos for carbohydrates, polys
14 for carbohydrates, saturated for monos, et
15 cetera, et cetera, and in terms of the change
16 of CHD risk from this epidemiologic study you
17 can see that there are various substitutions
18 that have a wide range of impacts on change,
19 particularly down below where the three
20 saturated fats traded for monos and polys and
21 the *trans* fatty acids for mono and poly
22 unsaturates, obviously, have sizeable

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1 reductions in cardiovascular risks. So the
2 search of the literature was particularly
3 focusing on updating this literature since the
4 2005 guidelines.

5 So for the first question, the
6 inclusion criteria obviously for the
7 monounsaturated literature looked at
8 literature since 2004. You can see the
9 inclusion criteria here. The healthy
10 population and those with chronic disease
11 risk. Now the study design really excluded
12 cross-sectional studies because of the many
13 biases you have in eating patterns, so we are
14 particularly looking at randomized control
15 trials or controlled clinical studies,
16 prospective studies, meta-analyses and
17 systematic reviews. We really did require a
18 feeding period of more than four weeks, and at
19 least 10 patients, 10 persons per study group.

20 So with the review of this
21 literature since 2004, the top 11 studies have
22 to do with the isocaloric substitution models

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1 for saturated fats; the five studies below are
2 in individuals with isocaloric substitutions
3 of monos for carbohydrates. And you can see
4 from the next slide there are two outcomes.
5 This was an expansion over the 2005 guidelines
6 which focused on cardiovascular disease,
7 cardiovascular disease risk, and given the
8 diabetes epidemic as well as the literature in
9 this area, type 2 diabetes was added as a
10 second study outcome.

11 And you can see here that of the
12 randomized control trials, five were positive
13 and three were neutral. Some of these studies
14 had endpoints with intermediary markers for
15 cardiovascular. Those are particularly the
16 proteins, but some inflammatory markers as
17 well, and also the two positive - two studies
18 for intermediate markers, type 2 diabetes,
19 those would be a variety of measures of
20 insulin resistance, et cetera. Also the four
21 studies, meta-analyses, were also supportive
22 of improved risk for cardiovascular diseases.

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1 So our draft conclusion statement,
2 and this was particularly assisted by some of
3 the large epidemiologic studies and meta-
4 analyses, we were looking at the energy
5 replacement, our draft statement: Dietary
6 monounsaturated fatty acids are associated
7 with improved health outcomes related to both
8 cardiovascular disease and type 2 diabetes
9 when monounsaturated fatty acid is a
10 replacement for dietary saturated fatty acids.

11 The evidence shows that 5 percent energy
12 replacement of saturated fats with
13 monounsaturated fats decreases intermediate
14 markers and risk of cardiovascular disease and
15 type 2 diabetes in healthy adults. It also
16 improves insulin response, in insulin
17 resistant and type 2 diabetic subjects.

18 This is particularly relevant to
19 some of the modeling studies we will be
20 talking about later with about 11 percent of
21 energy in the American diet as saturated fats,
22 which has been quite stable over the last 15

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1 or even 20 years, and replacement of 5 percent
2 would obviously be in the 7 percent or less
3 saturated fat range. So we feel that this
4 Grade I evidence.

5 The second part of this question
6 really looked at replacing a high carbohydrate
7 diet with a high MUFA diet in type 2
8 diabetics. This had five randomized trials,
9 two were positive quality, and three were
10 neutral. All five supported the conclusion
11 that MUFA replacement would be beneficial,
12 that included intermediate markers of fasting
13 glucose, hemoglobin A1C and the triglyceride-
14 rich glycoproteins. And the - also the high
15 MUFA diet was well tolerated.

16 So our conclusion statement here
17 would be: Increased MUFA intake, rather than
18 high carbohydrate intake, may be beneficial
19 for type 2 diabetics. High MUFA intake, when
20 replacing a high carbohydrate intake, results
21 in improved biomarkers of glucose tolerance
22 and diabetic control. And we felt that was

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1 Grade II evidence.

2 So the implications of this is
3 that there are - there really are isocaloric
4 in the study design, and so it may assume
5 these isocaloric changes. We are all very
6 aware of the nutrient - the caloric density of
7 fats, and this obviously needs to be taken
8 into account, so we are attempting to factor
9 this in to maintain an ideal body weight.

10 The high MUFA diets were well
11 tolerated in these studies, and the favorable
12 changes in glucose tolerance, inflammatory
13 markers, such as the lipoprotein, were all
14 common in diabetics, and they have health
15 implications around the diabetes and
16 cardiovascular disease.

17 The issues for future research,
18 and this is going to come up on the flip side
19 of looking at n-6 PUFAs versus MUFAs. And
20 really the question is sorting out which of
21 those two is more effective in decreased
22 cardiovascular and diabetes risk. And we do

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1 need additional studies with MUFA replacing
2 carbohydrate and relating to cardiovascular
3 disease in type 2 diabetes clinical endpoints
4 rather than the intermediary metabolic
5 endpoints.

6 So let's move on to the n-6
7 polyunsaturated fatty acids. And the question
8 here is what is the effect of dietary intake
9 of n-6 polyunsaturated fatty acids on risks of
10 cardiovascular disease and type 2 diabetes,
11 and again looking also particularly in the
12 randomized control trial literature for
13 intermediate health benefits of lipid levels,
14 lipoprotein levels, markers of inflammation
15 and blood pressure.

16 Of the inclusion criteria they
17 were virtually the same as the MUFAs, so I'm
18 not going to go over them again, excluding
19 cross-sectional studies. There were 10
20 studies in the literature, five randomized
21 control trials, four prospective cohort
22 studies, and one meta-analysis, since the 2004

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1 period. And you can see that six of the 10
2 studies were positive while four were neutral.

3 And generally the PUFA replacement of
4 saturated fat as a percent of energy improved
5 the intermediate markers, and the endpoint
6 health outcomes.

7 So the actual studies are seen
8 here. We do have randomized control trials.
9 Again this is mostly intermediate markers.
10 But again, but very I think very well
11 established, particularly the lipoprotein
12 markers, as being part of the causal pathway
13 between dietary fat and cardiovascular disease
14 event.

15 You could also see the one of the
16 clinical trials also had a type 2 diabetes
17 outcome with intermediary and glucose insulin
18 resistance markers.

19 The core studies looked at risks
20 of these chronic diseases, and you can see
21 that all four of those studies reported the
22 conclusion of improving risk with trading

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1 PUFAs and MUFAs for MUFAs for both
2 cardiovascular disease and diabetes after
3 meta-analysis.

4 So our draft conclusion statement
5 then is that the n-6 polyunsaturated fatty
6 acids are associated with improved health
7 outcomes related to cardiovascular disease
8 when replacing dietary saturated fatty acids
9 or trans-fatty acids. The evidence that as
10 you replace saturated fats with PUFA it
11 decreases total cholesterol, LDL cholesterol
12 and triglycerides, numerous markers of
13 inflammation. They also in epidemiologic
14 studies significantly decreases cardiovascular
15 disease risk, and at least one study, risk of
16 type 2 diabetes. So this is a Grade I
17 conclusion.

18 The implications again very
19 parallel to the ones for monounsaturated fats,
20 is that these also assume an isocaloric
21 replacement of polyunsaturated fats. The
22 risks of both cardiovascular disease and type

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1 2 diabetes may be reduced with PUFA replacement
2 for saturated fats and *trans* fatty acids, or
3 carbohydrates, and the mechanisms for
4 cardiovascular risk protection which includes
5 serum lipid levels, markers of inflammation,
6 maybe have additional health benefits being
7 picked up or examined in these cohort studies
8 or randomized trials.

9 So again the flip side of the
10 others is really to try to sort out, and it
11 may be a very difficult task in comparing
12 them, hence PUFAs with MUFAs, in terms of the
13 effects on cardiovascular and type 2 diabetes
14 risk. But given the distributions of these
15 and their sources in whole foods, it will be I
16 think an important area for future research.

17 Okay, now I think we can move on.

18 Is there any discussion at this point?

19 DR. APPEL: Yes, Tom, this is
20 Larry. One sort of detailed question and one
21 sort of general picture. Aren't there some -
22 and maybe Eric can comment - some already fair

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1 amount of cohort studies dealing with the MUFA
2 versus the PUFA issue at this point? Because
3 your research recommendations basically that
4 we need to do research in this area, but I
5 think it's mostly we need to do some trials in
6 this area, but there is evidence from cohort
7 studies.

8 DR. THOMAS PEARSON: I think I
9 was particularly talking about the need for
10 head-to-head randomized trials. But Eric, any
11 comments?

12 DR. RIMM: Yes, Larry, I mean I
13 think that is a good point. One issue when
14 people think of MUFAs in this country, or as
15 scientists when we think of MUFAs; we think
16 olive oil and canola oil, but that is not
17 where most of our MUFAs come in this country,
18 although a lot of it comes from red meat or
19 other places. So I think what we really want
20 to do as we said here, I think it really would
21 be a head-to-head comparison more than trying
22 to dissect the existing diets of the U.S.

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1 population.

2 DR. THOMAS PEARSON: I think the
3 observational studies are very difficult to do
4 without - and some of the studies as we'll
5 talk about later, the Lyon study, et cetera,
6 were steps in the right direction, but I think
7 really fell short for a variety of reasons
8 from what we wanted to look at in this
9 particular question format.

10 DR. APPEL: And then a more
11 detailed issue is, the - when I looked at the
12 MUFA or the question - the MUFA question talks
13 about intermediate outcomes such as
14 inflammation. I hope that it's not the
15 inflammation results that are driving the
16 conclusion, because I guess I may be more of a
17 purist on this one, but we probably should be
18 focusing on accepted modifiable risk factors.

19 Because at least the summary tables don't
20 mention, it just says it improves intermediate
21 outcomes without stating blood pressure,
22 lipids.

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1 DR. THOMAS PEARSON: Yes,
2 obviously the full tables with the outcomes,
3 obviously, get down to that level of
4 granularity. I think the important point is
5 that they are all essentially heading in the
6 right direction. And as you know I've been
7 involved with some of the inflammatory
8 biomarker guidelines, so I will agree with
9 your point that the full understanding of the
10 meaning of what changes an inflammatory marker
11 is still a raging debate. On the other hand
12 they certainly on a correlational population
13 basis the - they are a modestly useful
14 indicator of cardiovascular risk heading one
15 way or the other.

16 The single largest data here are
17 the lipids and lipoproteins, and that really
18 is I think beyond reproach in terms of really
19 being a significant intermediary indicator of
20 the chain of causation going in a positive -
21 that is a beneficial direction, if you are
22 able to change LDL cholesterol.

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1 DR. APPEL: Okay.

2 DR. PI-SUNYER: Tom this is
3 Xavier. With regard to the MUFA conclusions
4 relating to type 2 diabetes, I know that you
5 said that this was isocaloric substitution,
6 but I think somehow that might be in the
7 conclusion statement more strongly because you
8 know the fear is that these people are all
9 obese to start with, and if they had MUFA they
10 add more calories, and a lot of the MUFA foods
11 are high in calories and energy dense. So I
12 think somehow it would be important to caution
13 the need for isocaloric substitutions.

14 DR. THOMAS PEARSON: Yes, Xavier,
15 we obviously put it in the implications. But
16 I think putting it right into the conclusion
17 is correct, as we have struggled with as you
18 know with the total fat consumption, and so we
19 have been particularly focusing on the quality
20 of fats, and therefore replacing them on a
21 calorie for calorie basis, one fat with
22 another, in terms of our recommendations.

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1 Okay, can we go to the n-3 fatty
2 acids within plant sources, and Eric Rimm will
3 lead this discussion.

4 Eric.

5 DR. RIMM: Thank you, Chairman
6 Pearson, I will move on. Okay, n-3 fatty
7 acids, we are going to - next slide please -
8 address several different research questions.

9 One is what is the relationship between
10 consumption of seafood and seafood-derived n-3
11 fatty acids, so we will be focusing on foods
12 only here. And the risk of CVD events in
13 individuals without cardiovascular disease and
14 those with cardiovascular disease.

15 And a second question we will
16 address is what is the relationship between
17 the consumption of a plant derived n-3 fatty
18 acid diet and the risk of CVD in subjects with
19 and without cardiovascular diseases. Next
20 slide.

21 I will go over this quickly, but
22 for the most part our inclusion criteria was

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1 based on updating a previous ADA systematic
2 review of the evidence, and then adding on the
3 NEL review from 2007 forward, and like other
4 studies, other searches, we've excluded for
5 the most part cross-sectional studies, and
6 looked at cardiovascular endpoints for this
7 set of questions because of the WCRF summary
8 two years ago on cancer where overall looking
9 at all the seafoods the strongest evidence
10 they had is that there is limited and
11 insufficient evidence to suggest that fish
12 consumption lowers risk of colon cancer, so we
13 focus on cardiovascular disease only.

14 So the first question is, what is
15 the relationship between seafood in subjects
16 without cardiovascular disease. Next, please.

17 Our draft conclusion statement
18 here is that consumption of two servings of
19 seafood per week, which is approximately three
20 to five ounces per serving, which provides on
21 average 250 milligrams per day of n-3 fatty
22 acids is associated with reduced cardiac

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1 mortality from coronary heart disease or
2 sudden death in persons without previous
3 cardiovascular disease, and we've given this a
4 Grade II.

5 The review of the evidence here,
6 I don't have them all listed, Joanne did that,
7 we didn't do that here, there are a lot of
8 studies, there were 27 in total, four
9 randomized control trials, 15 prospective
10 cohort studies, a number of meta-analyses.
11 In fact this is one of the favorite for people
12 to do meta-analyses on, so we have six
13 systematic reviews or meta-analyses.

14 For the most part again we are
15 focusing on seafood and seafood-derived n-3,
16 so for the randomized control trials there
17 were several of them looking at primary
18 prevention, essentially looking at improved
19 biomarkers for cardiovascular disease,
20 improved blood pressure, and reduced risk in
21 cardiovascular disease. We name several
22 cohort studies. Sort of a mixed bag here,

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1 those that found an association found a
2 decrease incidence risk, and that is where the
3 primary number of studies were. A few found
4 no association when we're looking at a fib,
5 and one found no association with stroke
6 mortality.

7 Systematic reviews for the most
8 part found that fatty fish consumption in the
9 range that we are talking about of
10 approximately two servings per week on
11 average, or about 250 milligrams per day,
12 decrease cardiovascular disease and
13 cardiovascular events. Next slide.

14 So the implications for this, as
15 we started drafting future research here, is
16 that the consumption of seafoods high in n-3
17 fatty acids and low in methyl-mercury and
18 other pollutants is desirable and feasible.
19 Another implication of this obviously will be
20 that we need efficient and eco-friendly
21 strategies to continue to be developed to
22 allow for greater consumption of seafood and

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1 seafood-derived n-3 fatty acids across the
2 population and then further research is
3 needed, especially from randomized control
4 trials that are looking specifically at
5 increased consumption of seafood as opposed to
6 giving individuals n-3 supplements.

7 Next slide. And then second
8 question, part of this, is what is the
9 relationship between consumption of seafood
10 and seafood-derived fatty acids and risk of
11 CVD and individuals with cardiovascular
12 disease. And this is secondary prevention.
13 Next slide.

14 The draft conclusion here is that
15 the consumption of two servings of seafood per
16 week which provides an average of 250
17 milligrams per day is associated with reduced
18 cardiac mortality from CVD or sudden death.
19 And I think we are actually wavering back and
20 forth in Grade I or Grade II here. And as I
21 was reading it and thinking about it, I forget
22 why we didn't do this, call it a Grade I, and

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1 maybe we can have some discussion on that,
2 because I think this is where there is the
3 strongest evidence. Next slide.

4 The review of the evidence here
5 where there are four studies, three
6 prospective cohort studies, one meta-analysis,
7 and again we are building on the ADA evidence
8 analysis, and also in fact on the 2005 dietary
9 guidelines submitted. Next slide.

10 Here there were three cohort
11 studies that found a protective effect of
12 fish-derived n-3 fatty acids on risk for CVD,
13 and found reduction in all cause mortality,
14 although some of the associations were not as
15 strong here, and in this particular case
16 overall did not find associations with
17 combined fatal and non-fatal cardiovascular
18 events.

19 If you look at the systematic
20 review overall associated, we do stress for
21 nonfatal myocardial infarction. I guess that
22 was the key issue here, is that if we are just

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1 talking about fish and fish-derived fatty
2 acids, there are fewer studies than just those
3 that gave an n-3 fatty acid supplements. Next
4 slide.

5 Our implications here the same as
6 the implications, and certainly wrapped
7 together with the implications in the first
8 part of this question, is that we do need a
9 fish and eco-friendly strategy to continue to
10 develop ways to increase the consumption of
11 seafood and seafood-derived n-3 fatty acids,
12 and again I think it would be helpful here to
13 have randomized control trials to determine
14 the long term health effect of the
15 recommendation to increase consumption of
16 seafood in individuals with previous
17 cardiovascular disease.

18 DR. NELSON: Eric, this is
19 Miriam.

20 DR. RIMM: Yes.

21 DR. NELSON: Can I ask you a
22 quick question here? Is there any - you had

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1 put in the conclusion slide it was a certain
2 amount. Is there a dose response here at all?

3 I mean more is better, or is it actually sort
4 of a threshold.

5 DR. RIMM: This is one of the
6 areas where there is apparently it looks like
7 an apparent threshold. It's difficult to know
8 biologically but when we put all the studies
9 together you can see there is a huge drop in
10 the risk of cardiovascular mortality up to
11 that range of 250 - 300 milligrams per day,
12 and then as -- there are studies that go way
13 out, if you look at the Japanese study people
14 eat a gram or two grams per day, they don't
15 see as much benefit; and sometimes they see no
16 benefit.

17 DR. NELSON: Okay, great, thanks.

18 DR. RIMM: So that's how we
19 picked that. That was based on a few other
20 meta-analyses that were done sort of at an
21 inflection point.

22 DR. NELSON: Got it, thank you.

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1 DR. RIMM: Okay. So our next
2 thought is to look at what is the relationship
3 between the consumption of plant-derived n-3
4 fatty acids and the risk of CVD events in
5 subjects without CVD. And here there was less
6 evidence. WE felt that the plant - the main
7 plant-derived n-3 fatty acids is alpha-
8 linolenic acid, and intake here is alpha-
9 linolenic acid intake between point six and
10 one point two percent of total calories meets
11 the prior recommendations in the IOM Seafood
12 Report for essentially fatty acids, and may
13 lower CVD, but there is not sufficient new
14 evidence to warrant greater intake beyond this
15 level. That is a Grade II conclusion. Next
16 slide.

17 For this we reviewed the evidence
18 from eight studies, four were prospective
19 cohort studies, one was a systematic review,
20 and three were case controlled studies. Next
21 slide. And this is again, I've listed the
22 slide there, this is a mix of studies. Some of

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1 it is based on diet, some of it is looking at
2 fatty acids in adipose and other areas. But
3 in most part, for instance, the Rastogi study
4 was an interesting one because it was ALA oil
5 for cooking, lower risk of ischemic heart
6 disease, but it wasn't in this country, so it
7 was a different type of ALA and a very
8 different background type of diet. The other
9 studies have found a membrane ALA associated
10 with changes in sudden cardiac disease.
11 Looking at the cohort studies, again, these
12 are prospective studies from several different
13 areas around the country, several of them
14 finding lower risk of cardiovascular disease
15 from higher ALA, others did not find an
16 association for serum ALA, dietary ALA or ALA,
17 and then the meta-analysis in 2006, overall
18 did not include that increased intake of ALA
19 does not reduce the rate of all-cause
20 mortality in cardiac or sudden death, sudden
21 cardiac death.

22 So I think there is a mixed bag

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1 here. There was some suggestion, but overall
2 not a strong enough statement for us to make
3 as Grade II evidence. Next slide. The
4 implications for this is currently there is
5 insufficient evidence to increase n-3 intake
6 from plant sources. We all have discussed in
7 the past that there is low conversion from
8 plant n-3 to marine n-3, so we do I think need
9 further evidence from randomized controlled
10 trials and prospective observational studies
11 among participants with a broad range of entry
12 intake, especially with and without adequate
13 intake of n-3 fatty acids from marine sources.

14 On this point, and something that we have
15 discussed before, clearly there are many
16 populations in the world that in the U.S.
17 where people don't eat fish, and they are not
18 walking around with n-3 deficiency type
19 diseases. So people do convert enough of
20 the plant sources to the longer chain entry
21 fatty acids. The question is are they getting
22 maximum benefit, and I think we don't know

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1 that, so I think it is interesting to be able
2 to make suggestions for research in the future
3 to be able to look at ALA among populations
4 who have no n-3 from fish, have moderate
5 amounts from fish, and have larger amounts
6 from fish, to see if there really are
7 differences in subsequent risk for disease as
8 well as differences in conversion.

9 Next slide: so lastly we wanted to
10 look at what is the relationship between
11 consumption of plant-derived n-3 fatty acids,
12 and risk of cardiovascular diseases in events
13 subject with CVD. Next slide.

14 And for the most part here this is
15 the Lyon heart study. So our conclusion is,
16 there is limited evidence that higher intake
17 of n-3 from plant sources may reduce mortality
18 among individuals with existing cardiovascular
19 disease. We gave this a Grade III. Next
20 slide. And again this is the Lyon heart
21 study. And overall while this did find a
22 protective effect, this was not a trial solely

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1 on ALA. This is one of the things we use in
2 the interventions, but there were other
3 factors in the intervention, so we can't call
4 this strictly an ALA trial. Next slide.
5 Plasma ALA tended to be inversely associated
6 with recurrence of MI because ALA was put into
7 a margarine, into a spread, in the Lyon study.
8 Next slide.

9 So our research recommendations
10 here are again while we can look at
11 observational studies, I think it is important
12 in the secondary prevention study. I think
13 randomized trials are needed to examine the
14 impact of higher intakes of n-3 from plant
15 sources in reducing mortality from CVD.

16 And locations from this is
17 relatively little ALA converts to EPA or DHA,
18 suggesting that plant-derived n-3 fatty acids
19 and on a gram-per-gram basis alone may not
20 provide the cardiovascular protective effect
21 that we've seen through DHA or EPA. So this
22 insufficient evidence to make a formal

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1 guideline to increase n-3 intake from plant
2 sources, without additional randomized
3 clinical trials and/or prospective studies,
4 among participations across a broad range of
5 n-3 fatty acid intake. Next slide. Is that
6 the end for me? Yes, that is the end for me.

7 DR. THOMAS PEARSON: Why don't we
8 open it up for some questions at this point.
9 I did want to make one comment, and that is
10 that this issue of efficient and eco-friendly
11 strategies for assuring the source of n-3
12 marine fatty acids, it was quite an interest
13 of a speaker at the recent cardiovascular
14 epidemiology meetings, the health effects of
15 various health policies in the UK. And he had
16 not made a recommendation on fish and was
17 asked that question in the discussion period.

18 And it really dealt with this issue, that the
19 feeling was that they recommended to the
20 British Isles population to increase the
21 intake of fish that they would deplete the
22 entire region of fish sources. So I think the

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1 fish while an efficient and eco-friendly
2 strategy for the supply of fish is a very
3 important one when we start talking about
4 these recommendations.

5 DR. NICKOLS-RICHARDSON: This is
6 Shelly. I have a question, and I do
7 understand the emphasis here on food based
8 sources of DHA/EPA. But did the Committee
9 look at some of the supplements, trials,
10 anything? Does the fish recommendation with
11 the 250 milligrams per day equate to what the
12 supplement studies were showing?

13 DR. RIMM: That is a good
14 question, Shelly. The supplement studies are
15 little more challenging, because they don't
16 have - they are not like supplement studies
17 that have a beautiful dose response across the
18 range. Most of them give quite a fair bit,
19 and most of them are giving a gram or more.
20 So it's more challenging to look at a
21 threshold effect below that.

22 But I think in the back of our

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1 mind when we are writing the conclusion
2 statements, we are knowledgeable about the
3 relatively strong evidence for the supplements
4 for the trials at higher levels. But I think
5 if all those had found no association we would
6 definitely not be as comfortable giving the
7 conclusion about n-3 from seafood. The point
8 is that I think we want to recognize that fish
9 is not just a source of n-3. It's also a
10 good protein package, as well as - contributes
11 to other components of the diet, so that is
12 why we wanted to focus on fish. But I do
13 appreciate the fact that the supplement trials
14 exist.

15 DR. NICKOLS-RICHARDSON: Okay,
16 and we will address that with nutrient
17 adequacy, but I just wanted to get your sense
18 of looking at those trials, what - how did the
19 levels sort of stack up there?

20 DR. RIMM: Yes, they don't make
21 supplements across the whole range.

22 DR. NICKOLS-RICHARDSON: Yes.

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1 DR. APPEL: This is Larry to
2 follow up on that question. I did read the
3 conclusion and then compare that to the
4 question, and it - the question deals with
5 marine n-3 fatty acids, and the conclusion is
6 seafood, but I'm just wondering if you should
7 change it to seafood, because I think that as
8 you pointed out Eric, you do have like the GC
9 Prevention that shows a benefit from the
10 supplements. And I think your conclusion is
11 really more based on the food.

12 DR. RIMM: So what are you saying
13 we should change?

14 DR. APPEL: Well, it says - the
15 seafood-derived fatty acids. You don't really
16 - you could have two types of conclusions, one
17 for seafood and one for the fatty acids. Your
18 conclusion is really the seafood and not the
19 fatty acid.

20 DR. RIMM: Yes, I guess so we
21 should say n-3 - seafood containing n-3 fatty
22 acids, throughout --

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1 DR. APPEL: Yes, and potentially
2 drop the --

3 DR. RIMM: Seafood derived?

4 DR. APPEL: -- seafood derived
5 fatty acids from your caution, because that is
6 not what you are testing here, or at least
7 that is not your statement in your conclusion.

8 DR. RIMM: Yes, that's a good
9 idea. Shirley, can you make note of that. I
10 think you are right. We went back and forth
11 on this, and then really consciously said,
12 look, we're talking about this as a dietary
13 guidelines; we're talking about food. And I
14 don't know how the seafood-derived snuck in
15 there unless - but you are right, I mean most
16 of the supplements are seafood-derived
17 supplements, so we should not - we should take
18 that out I guess.

19 DR. APPEL: And you would reach
20 an Evidence I conclusion I think at least in
21 those with CVD for that one.

22 DR. RIMM: Yes, I mean the

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1 problem is, there are not a lot of trials on
2 fish; that's why I think we backed down to
3 Grade II. Because there is a lot of
4 observational data. Some trials are shorter
5 term on a few. But to do a long term trial on
6 randomizing people to fish per se, there are
7 some on fish advice, but that usually invites
8 and includes other things. And that's why we
9 shied away from it. But I'd be happy to call
10 it a Grade I if everybody felt the evidence
11 was strong enough. I mean I think that's what
12 the 2005 dietary guidelines struggled through.

13 DR. APPEL: Yes, no I think your
14 Grade II is fine, but I - the way I would deal
15 with it would be to just drop seafood-derived
16 fatty acids from your question.

17 DR. RIMM: Thanks.

18 DR. APPEL: You're not saying
19 omega 3 or omega - you're talking about fish.

20 DR. RIMM: Great.

21 DR. THOMAS PEARSON: There
22 clearly is an assumption that this is the

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1 intermediary mechanism, and obviously there
2 are many other things - taurine, and a variety
3 of other - selenium components, et cetera -
4 that it is in the fatty acid section rather
5 than the protection section because of that
6 just to point out -

7 DR. POST: This is Bob Post. I've
8 got a clarification request for Tom, and this
9 goes back to the slide on n-6 PUFA
10 implications.

11 DR. THOMAS PEARSON: Okay.

12 DR. POST: Specifically the first
13 bullet. It's a rewording. It might be stated
14 backwards. So we are suggesting, all
15 recommendations assume an isocaloric
16 replacement of saturated fatty acids or trans-
17 fatty acids with PUFA. That's the more
18 correct way of stating the first bullet.

19 DR. THOMAS PEARSON: Okay, we
20 will make a note of that. I see what you
21 mean.

22 DR. POST: Great, thanks.

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1 DR. THOMAS PEARSON: Okay, let's
2 move on. And our next topic is a new one, we
3 go on to, and that is to look at fatty acids
4 from seafood on breast milk composition, and
5 infant health outcomes. This is a new
6 question, but one which I think as you will
7 see from Roger Clemens when he presents this
8 is, we've got a lot of evidence in support of
9 it. Roger.

10 DR. CLEMENS: Thank you so much,
11 Tom, and thank you so much, Eric, and the
12 entire fatty acid team.

13 This is very important topic.
14 It's received a great deal of attention from
15 the public. It's obviously received a great
16 deal of attention and questions from the
17 medical community. So we thought it was
18 important that we started providing direction
19 and guidance on this particular issue. And
20 certainly maternal diet.

21 And you will find that as we look
22 at the kinds of data that we think we

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1 actually see consistency across the board
2 relative to recommendations in terms of
3 accuracy, I think fatty acids as well as the
4 food safety issue, and that food safety issue
5 will be addressed tomorrow by our colleagues
6 Rafael.

7 Obviously maternal diets
8 containing n-3 fatty from seafood that was
9 investigated across the last 10 years. We are
10 looking at the healthy population of pregnant
11 and lactating women, and certainly went to
12 examine the mother-infant pairs. We examined
13 several RCTs and controlled studies, meta-
14 analyses, very systematic reviews. Hopefully
15 feeding periods of more than four weeks. The
16 four weeks was chosen because that's when you
17 begin to see some differences metabolically.
18 Obviously sample size of greater than 10 are
19 consistent with our original criteria.

20 And the exclusion criteria not to
21 confuse and in an attempt to separate the use
22 of food versus that of dietary supplement that

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1 contains the various n-3 fatty acids, and of
2 course across the board we've excluded various
3 cross-sectional studies that might be
4 published. Next slide.

5 So in review of the evidence we
6 examined nine studies, seven of which were
7 prospective cohort studies. We have a balance
8 there of one RCT and one meta-analysis.

9 And the balance here there were a
10 couple of positives and most of them were
11 neutral including the RCT, yet in the meta-
12 analysis we see a positive association which
13 we indicate in the next graphic. This graphic
14 indicates the distribution and the type of
15 outcomes that have achieved great attention.
16 Most of the attention has been directed to
17 visual acuity and neurological development, as
18 well as a variety of biomarkers such as methyl
19 mercury and the risk benefits associated with
20 consuming fish and relative to the exposure of
21 methyl mercury and the n-3 fatty acid
22 analysis. And throughout the RCTs and the

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1 meta-analysis again we are looking at
2 cognition, visual acuity, as well as when we
3 come to women who are nursing their children,
4 we want to look again at the impact on the
5 composition of breast milk and how that
6 composition can be changed by fish
7 consumption, and obviously through fish
8 consumption the end that changes the
9 composition relative to DHA and relative to n-
10 3 fatty acids.

11 Next. Based on those studies we
12 see that in fact we have increased maternal
13 dietary intake of long chain fatty acids,
14 particularly n-3, and particularly DHA from
15 two servings of seafood a week. That goes out
16 to the three to five ounces twice a week to
17 which Eric referred. During pregnancy and
18 lactation is in fact associated with improved
19 infant health outcomes, such as we measure
20 visual acuity and neurological and cognitive
21 development. And we also we might expect, and
22 we do see it, an increased DHA levels in

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1 breast milk.

2 Based on the evidence we have
3 right now we believe this is a Grade II.
4 These kinds of today's the word is Grade II.
5 Next.

6 And that's it.

7 DR. THOMAS PEARSON: Let me just
8 point out, Roger is going to be back with our
9 seafood modeling question later talking about
10 what diets with this two servings a week might
11 look like, and so there will be some further
12 comment on this. Is that fair, Roger?

13 DR. CLEMENS: That's' fair to
14 say. Thank you.

15 DR. THOMAS PEARSON: Questions?

16 DR. PI-SUNYER: Roger, I just
17 have a comment on your wording here.
18 Shouldn't you put it improves infant health
19 outcomes, shouldn't you put during pregnancy
20 and lactation showing that the increased DHA
21 levels in breast milk and then go on to say
22 that that risk is associated with improved

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1 health outcomes? Isn't it backwards? I mean
2 the mother eats the food and it gets into the
3 breast milk and then it gets into the baby and
4 then it causes improvement.

5 DR. CLEMENS: That is a good
6 observation. Thank you so much, and I will
7 certainly make that adjustment.

8 DR. APPEL: This is Larry, and
9 this is really interesting to me, but I am
10 also trying to process this in comparison to
11 the other databases where there is a lot more
12 evidence. This comes across as a pretty
13 strong conclusion, I know it's Grade II. I
14 mean are these - we haven't drilled down on
15 the individual studies - they are not clinical
16 trials, but are these cohort studies well
17 designed with potential confounders dealt
18 with? I think this potentially could get a
19 lot of attention the way this is worded?

20 DR. CLEMENS: I really believe we
21 are, Larry, and I appreciate the remark.
22 These kinds of studies, we went back 10 years

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1 as you saw, I had worked in this particular
2 area for 20 or 30 years, as you have in your
3 particular area of expertise. And this is
4 consistent with all the data if we were to go
5 back even 20 or 30 years, and most of the
6 attention has received a great deal of
7 research effort in the last 20 years, so we
8 examined this the last 10 years. So this is
9 consistent with the data presented in the IOM
10 report, and all the other reports that we
11 reviewed for this particular question.

12 DR. THOMAS PEARSON: I just
13 wanted to emphasize just recently the WHO and
14 some European bodies have weighed in on this,
15 again on the basis of recent strength of the
16 evidence, in further statements really just in
17 the last six months or so.

18 DR. CLEMENS: Indeed, the pharma
19 group, the EFSA group out of Parma, Italy,
20 certainly weighed in on this. And this
21 statement is actually supported by the
22 European group on this particular issue.

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1 DR. NICKOLS-RICHARDSON: This is
2 Shelly again, just the same sort of question
3 about the supplement trials. I think my
4 understanding of the supplementation trials is
5 that the level is a little bit higher, 300 to
6 500 milligrams of DHA per day. So again did
7 you guys look at some of that supplement data,
8 and I understand again dropping that because
9 you want to look primarily at the food first,
10 and I am very supportive of that. But just in
11 terms of evidence, and how that fits with the
12 supplementation and making the case for food
13 versus supplementation during pregnancy and
14 lactation.

15 DR. CLEMENS: I certainly
16 appreciate that, Shelly. And frankly we've
17 really focused on the food outcomes. We
18 really try to tease away the implications that
19 it might have on the dietary supplement side.

20 Clearly as Tom and Eric have indicated, there
21 are many many studies that have been conducted
22 with supplements, and many of those

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1 supplements it is nicely stated that they were
2 in fact conducted with doses much higher than
3 this.

4 DR. NICKOLS-RICHARDSON: Okay.

5 DR. NELSON: Shelly, it seems
6 like in our conversation yesterday in our
7 subcommittee that this is in agreement with
8 the supplement studies as well. As he said,
9 it's higher in some of the supplement studies,
10 correct?

11 DR. NICKOLS-RICHARDSON: Yes, and
12 again I think it will be consistent and these
13 two pieces will hang together. And again I do
14 want to advocate the total diet, the diet
15 approach first, but also recognizing that, if
16 the benefit is really from a little bit higher
17 level, then what is the balance in the fish
18 consumption related to some of the health
19 risks related to heavy metal.

20 So I just want to make sure that
21 the food recommendation fits with the key
22 outcomes from the supplement trial so that we

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1 are recommending a level in food which is
2 equivalent and would provide some benefit.

3 DR. THOMAS PEARSON: I think the
4 food safety group on which Roger also sits,
5 and I think Rafael is going to comment on this
6 later, but also with the seafood modeling
7 exercise, I think it all does fit together,
8 and as the two days come together, I think it
9 is going to be very clear that we have all
10 talked together and think the benefit-to-risk
11 ratio is in favor of fish consumption. And
12 some of the food modeling provides us insights
13 as to what that diet would look like.

14 DR. RIMM: This is Eric. Larry,
15 I think you have a really important question,
16 because we don't want to make a strong
17 statement without being able to back it up.
18 And I think it's actually in the accounting
19 for the heavy metals and other covariants that
20 the signal really comes through stronger, like
21 in the Project VIVA study that Emily Oken has
22 been working on for some time, the beneficial

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1 effect of the n-3 fatty acid on fine motor
2 skills and other outcomes is somewhat muted,
3 and then you account for mercury, and you can
4 see the n-3 benefits are a bit stronger
5 because there was a slight positive effect
6 from mercury. So I think overall you're
7 right, not every study does a great job of
8 dealing with covariants, but I think there are
9 a large number of them that carefully control
10 for potential confounders.

11 DR. WILLIAMS: I think the vast
12 majority of pregnant women now get their n-3
13 fatty acids from supplemental drugs.

14 DR. CLEMENS: Christine, Rog.
15 Yes, indeed. That has been my experience as
16 well, Christine. It seems that the medical
17 community has said, if it contains any methyl
18 mercury in the fish, they advise the patients
19 and moms wannabes to not consume any fish
20 whatsoever, and at the same time, then the
21 physicians and the patients and consumers
22 started examining the dietary supplement

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1 world, and do they come, do they screen even
2 for methyl mercury. And the answer is no,
3 typically. And Rafael will actually address
4 some of these very important issues on the
5 risk-benefit and the issues associated or
6 surrounding the methyl mercury issue.

7 DR. WILLIAMS: Would it be
8 preferable for women to get their n-3 fatty
9 acids from places rather than the supplements?
10 Is that what you are suggesting?

11 DR. CLEMENS: No, it's not what
12 we are suggesting. We really recommend that
13 we get them from food. To Eric and Tom's
14 earlier remarks, certainly fish are more than
15 just n-3 fatty acids. There's a hope - this
16 is important for natural development. For
17 instance, for better nutrition for mom.

18 DR. APPEL: This is Larry. I
19 think there are going to be a ton of issues
20 that this conclusion statement raises. This
21 is one of those where we probably should have
22 an implication slide or statement. Are you

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1 guys planning that, or were you planning on
2 sort of bundling that up after the food and
3 safety discussion?

4 DR. THOMAS PEARSON: The
5 implications, I think we could add that.

6 DR. APPEL: Because I think the
7 food versus supplement source is going to be
8 an important one and at least a cross-
9 reference to the mercury issue.

10 DR. NELSON: This is Mim. I
11 think that it will be important if we do that,
12 and I agree that we need to have an
13 implication statement, that we need to -
14 because this is, the supplement is dealt with
15 in the nutrient adequacy subcommittee, and the
16 food is dealt with here, in this chapter, I
17 think if we do have an implication statement
18 that we need to make sure that it's
19 coordinated in one, as opposed to two
20 different ones.

21 DR. CLEMENS: We certainly agree
22 with that, Mim, and we've done that, we

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1 examined the data across fields. And as a
2 matter of fact in this particular case the
3 fatty acid team has been working with the food
4 safety team to address this issue on methyl
5 mercury, and the other teams have done
6 similarly on related questions.

7 DR. NELSON: Yes, so, Shelly,
8 somebody just needs to make sure we keep track
9 of that.

10 DR. NICKOLS-RICHARDSON: Yes,
11 this is Shelly again, and I know this will
12 bring up some more discussions tomorrow,
13 because I think that this pregnancy/lactation
14 is one of those times during the lifespan when
15 we are going to at least from nutrition
16 adequacy suggest that supplementation may be
17 important. Just so you are prepared for
18 tomorrow and maybe think about it overnight.
19 So reflect a little on that, because we
20 certainly want to propose this consumption for
21 DHA as well as other nutrients.

22 DR. CLEMENS: And to your point,

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1 this is the first time we've gone beyond - or
2 younger than two years of age, and we are
3 addressing a very important topic of course,
4 that is, the health of moms and mom wannabes.

5 And the impact of their health on infants,
6 and Christine can chime in and sort of
7 reinforce that issue.

8 DR. THOMAS PEARSON: I'm coming
9 to the time. I think what we should do is go
10 on to the next one, and I think there will be
11 some opportunities with the seafood modeling
12 later if there is further discussion.

13 The group felt we had considered a
14 number of foods, whole foods, high in fats,
15 and a number of these have been elsewhere.
16 And so we were going to cover two of them
17 here, nuts and chocolate.

18 So the first question here is,
19 what are the health effects related to
20 consumption of nuts? The search criteria you
21 can see here has gone back to 2004, the NEL
22 and then the 2003. Children and adults, down

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1 to age two, healthy populations, again,
2 limiting it not to include cross-sectional
3 studies, so it's randomized controlled trials
4 and prospective studies and meta-analyses,
5 eating period of more than four weeks and
6 sample size of greater than ten, as we had
7 before. And the health outcomes included
8 both cardiovascular disease endpoints as well
9 as blood lipids and lipoproteins, measures of
10 glucose intolerance and insulin sensitivity in
11 type 2 diabetes incidence.

12 The interesting part of this
13 evidence is that nuts is obviously a whole
14 family of foods, so there are some studies
15 which just talk about nuts in general, and a
16 variety of nut types, and then there are
17 others particularly focused on specific nuts,
18 in which case, in this slide, almonds. So for
19 nuts including peanuts there is one systematic
20 review, five cohort studies and one randomized
21 trial. For almonds there are three randomized
22 trials and one meta-analysis.

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1 And just to say, there have been
2 17 studies all in general including many on
3 some of the other types of nuts. So here is
4 the walnuts, systematic review of three
5 randomized trials; macadamia, one trial;
6 pistachio, two randomized trials. And then
7 some of the other nuts may be represented in
8 their analyses.

9 So it's a bit of a diverse
10 evidence, particularly with the possibility of
11 nut-to-nut variation that one may expect on
12 the basis of their fatty acid composition et
13 cetera. Next slide.

14 Here are some of the health
15 effects related to nut consumption, and this
16 includes peanuts, which of course would be
17 frequently consumed not only as peanut butter
18 but also peanut oils, et cetera. Generally
19 what you can see is many of these prospective
20 cohorts compared to low consumers with the
21 times consumption per week, so the
22 quantification of nut consumption obviously is

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1 not only frequency but also quantity in
2 general, which you can see in the increased
3 consumption of nuts is related to reduced
4 clinical outcomes, cardiovascular disease in
5 particular, but also metabolic syndrome, et
6 cetera. And also an inverse relationship to
7 LDL cholesterol and total cholesterol.

8 And just to note the one
9 systematic review from earlier had 23 studies,
10 so there is a reasonable literature
11 particularly on all nut consumption.

12 Similarly with almonds, what you
13 have is with intermediary metabolites
14 decreasing total LDL cholesterol, one study
15 had also I think decreasing cholesterol, you
16 can see with particularly the intermediary
17 metabolites there, the favorable effects of
18 almond consumption. Next slide.

19 Similarly to walnuts, particularly
20 with lipid endpoints, some discussions of
21 weight also in the last randomized trial. The
22 one study on macadamia nuts, obviously you had

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1 some lipid benefits in pistachios as well.
2 Next slide.

3 So our draft conclusion statement
4 is the consumption of unsalted peanuts and
5 tree nuts, specifically walnuts, almonds and
6 pistachios, within an energy-balanced diet,
7 has a favorable impact on cardiovascular
8 disease risk factors, particularly serum
9 lipids. We gave that a Grade II. One of the
10 adjectives here is the unsalted with, as we
11 will talk about the implications, is this is
12 frequently a food which is served at least in
13 snack forms with added salt, and there wasn't
14 any discussion of those in most of these
15 trials, so the assumption is that the evidence
16 base had to do with unsalted peanuts and tree
17 nuts.

18 So if one were to look at the
19 range of consumption the nut consumption is in
20 the form of peanuts, and this is an important
21 source of plant protein and other nutrients in
22 addition to its oil, so it, I think, is an

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1 important issue to look at and perhaps make
2 recommendations about, and as we had said
3 before, many nuts are sold with added salts,
4 and obviously the limiting to unsalted nuts
5 would be a way to limit sodium intake.

6 Many of these trials were over
7 short periods of time, with intermediary
8 endpoints rather than clinical endpoints. So
9 it would be helpful to have longer studies
10 with health outcomes. And trying to make
11 distinctions between the types of nuts. Many
12 of these trials were funded by industry, and
13 so it would be well to have a broader and more
14 general comparison of the various nut meats to
15 look at health benefits.

16 Discussion on nuts?

17 (No response.)

18 Okay, why don't we go ahead, I
19 want to go on to chocolate, watching our time
20 here. And a similar question is, what are the
21 health effects related to consumption of
22 chocolate. Next slide.

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1 The inclusion criteria went back
2 to the year 2000, and both healthy and at-risk
3 individuals, again excluding cross-sectional
4 studies, same criteria as we have used in the
5 past. Thirteen studies over this 10-year
6 period were identified; three reviews with
7 meta-analyses, eight randomized controlled
8 trials, one cohort study and one population-
9 based case control study. Next slide.

10 Here you can see the evidence of
11 both the intermediate markers - many of those
12 were lipids - as well as cardiovascular
13 disease outcomes, and among the reviews,
14 particularly the Ding et al, was a - included
15 a larger number of previous studies, and a lot
16 of the section on particularly the flavonoids
17 in chocolate having a benefit on CHD and MI
18 mortality, particularly with some use of high
19 flavonoid versus lower flavonoid forms of
20 chocolate, but also there was evidence that
21 there are intermediate markers particularly
22 the lipids and lipo-proteins.

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1 The one study by Hooper looked at
2 flow -- diameters of vascular flow measures as
3 an intermediate measure, and there was the
4 Desch study looking at cocoa chocolate
5 improving blood pressure.

6 In terms of the randomized
7 controlled trials, you can see again the serum
8 lipids, blood pressure, blood flow
9 information, and generally a number of
10 positive studies showing improvement with
11 chocolate or cocoa, and there are two
12 observational studies with one neutral and one
13 positive quality with a relationship of cocoa
14 and chocolate consumption improving -
15 associated with reduced CHD/MI mortality.

16 So the draft conclusion statement
17 is that there are health benefits associated
18 with moderate consumption of some types of
19 dark chocolate or cocoa, that would be Grade
20 II evidence. Next slide.

21 The number of implications here,
22 many of these beneficial effects of chocolate

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1 have been attributed to the polyphenolic
2 compounds in the discussions of these papers,
3 et cetera. There is also obviously an
4 interesting fatty acid distribution in
5 chocolate with high amounts of stearic acid.
6 So really many plant foods contain
7 polyphenols, and chocolate is really a minor
8 source of it when you look at the whole diet.

9 This is a full fat food, and so potential
10 benefits obviously need to be balanced with
11 caloric intake. It's very clear that
12 particularly from a research standpoint making
13 sense of the data, formulations in chocolate
14 are known to have polyphenolic profiles, and
15 that is the mechanism. And different forms of
16 chocolate may confer different benefits. And
17 you should always keep in mind that this is -
18 the number of calories involved, the chocolate
19 is currently a small component of the total
20 diet, and any benefits from the food is likely
21 to be minimal.

22 DR. NELSON: Tom?

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1 DR. THOMAS PEARSON: Yes.

2 DR. NELSON: This is Mim. Can I
3 ask a question?

4 DR. THOMAS PEARSON: Sure.

5 DR. NELSON: Or if you want me to
6 wait, I'm happy to.

7 DR. THOMAS PEARSON: That's fine.

8 DR. NELSON: The conclusion, I
9 think it was the slide before, about moderate
10 amounts of - that there are health benefits.
11 I think that as we have done with the other
12 kinds of conclusions that within calorie
13 limits, or something like that, I mean I'm
14 worried about a conclusion statement like this
15 then you know, if it's not weighted a bit with
16 being careful about calorie intake, because a
17 lot of the chocolate has a lot of calories and
18 sugar as well.

19 DR. THOMAS PEARSON: A lot of the
20 studies were isocaloric. And certainly in our
21 implications slide we felt the need to make
22 this point as well.

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1 DR. NELSON: Where is it in the
2 next slide? I mean it was more that it's a
3 small amount. I think maybe it's in the
4 implications that it needs to be balanced -
5 okay, there, got it.

6 DR. THOMAS PEARSON: It's an
7 important point. Very high density of
8 calories.

9 DR. NELSON: Yes.

10 DR. PEREZ-ESCAMILLA: This is
11 Rafael. What is known about the impact of
12 saturated fat in chocolate vis-à-vis saturated
13 fat in animal products in relationship to
14 cardiovascular disease rate?

15 DR. THOMAS PEARSON: We - this
16 actually harkens back to something we have
17 presented previously relative to stearic acid
18 and the concept of cholesterol-raising fats.
19 Again, there are a variety - there is a range
20 of fatty acid distributions, but particularly
21 if you are talking about dark chocolate with
22 relatively little milk fat in it, you are

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1 talking about cocoa butter having upwards of
2 40 - 50 percent of its fat as stearic acid.
3 Stearic acid again, and this goes way back to
4 Ansel Keys and the early studies, really as we
5 had mentioned before does not have the
6 metabolic protective rate on the LDL
7 cholesterol that the other fats that are solid
8 at room temperature have, and so though it is
9 - if you were to use the old definition of
10 saturated fat, it would be a high saturated
11 fat compound food, but in effect, if you look
12 at the cholesterol-raising fats of chocolate,
13 again, upwards of half of it is stearic acid
14 which in fact is not a cholesterol-raising
15 fat; does that help?

16 DR. PEREZ-ESCAMILLA: Thank you
17 very much.

18 DR. APPEL: Tom, this is Larry.
19 I just wanted to follow up on Mim's comment.
20 I look at the implications in the draft
21 conclusion, and I'm a bit worried, because if
22 you go to the last line of the implications,

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1 you state: chocolate is currently a small
2 component of the total diet and benefits will
3 likely be minimal. I think - I don't want to
4 wordsmith, but it sounds as though it's a
5 small component, and because it's small,
6 benefits will likely be minimal. And I go to
7 the conclusion statement that moderate
8 consumption - and it seems like I need to
9 increase, because the benefits are small - or
10 minimal because it's a small amount of the
11 diet now. You might even want to just drop
12 the word, moderate, because I think people are
13 going to view that as increase.

14 DR. THOMAS PEARSON: I think one
15 is the evidence, and one is the particularly
16 randomized trial evidence, again, derived in
17 the evidence based conclusions, versus the
18 other one which has to do with more of
19 population based information.

20 DR. NELSON: It gets tricky.
21 This is Mim. I just think it's a bit tricky
22 here. I think also, what is - I mean what is

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1 moderate consumption? It is sounding like we
2 are trying - the implication is - I know it
3 sounds a little - it sounds like we are trying
4 to get people to eat more chocolate.

5 DR. APPEL: I agree; that's what
6 it sounds like.

7 DR. THOMAS PEARSON: A lot of the
8 randomized trials used, in a variety of forms,
9 more chocolate than would be ordinarily
10 consumed.

11 DR. NELSON: Right, and that may
12 be just a little bit unreasonable.

13 DR. THOMAS PEARSON: Yes.

14 DR. APPEL: Then you could put
15 that in the discussion. But I really worry
16 about this moderate term in the conclusion.
17 You could just leave it as consumption, then
18 talk about the range of distribution when you
19 talk about the articles.

20 DR. THOMAS PEARSON: Yes, I think
21 we could just talk about consumption, how many
22 times a week, rather than the grams or

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1 whatever.

2 DR. APPEL: Or not even get into
3 dose in the conclusion. I just think there is
4 a risk with this one more so than others.

5 DR. NELSON: I agree.

6 DR. CLEMENS: This is Rog. I
7 think Tom did a nice job of summarizing the
8 data. I think it's important that we also
9 understand when the term "dark chocolate" was
10 used, that not all dark chocolates are created
11 equal, and certainly to Tom's comments on the
12 polyphenolic content, that is clearly
13 dependent on how it's harvested, how it's
14 fermented, and how it's processed.

15 DR. THOMAS PEARSON: Right.
16 Okay, I think we have to watch our time here.

17 And let's move on, and Roger is going to
18 help us with the next topic, and that is the
19 ruminant versus industrial *trans* fatty acids.
20 Roger.

21 DR. CLEMENS: Thanks very much,
22 Tom.

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1 This basic question about *trans*
2 fatty acids was addressed in the 2005, the
3 2005 document did not differentiate the
4 ruminant versus industrial *trans* fatty acids.

5 With this becoming more of a question from
6 consumers and amongst the medical/scientific
7 community we thought it was incumbent upon us
8 to look at what data are in fact available,
9 hence the question, what effect do the
10 consumption of ruminant versus synthetic or
11 industrially produced *trans* fatty acids have
12 on various biomarkers relative to lipid
13 metabolism and cardiovascular disease.

14 In fact we find that many people
15 don't even know that there is a difference, in
16 fact that there are these things called
17 naturally occurring fatty acids, *trans* fatty
18 acids in foods. As we look at the next chart,
19 you will see here based on some data that we
20 were able to pull out thanks to our wonderful
21 team that these are the typical *trans* fatty
22 acids in a variety of products. These

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1 products - in fact the *trans* fatty acids in
2 these products are typically we could call it
3 an industrial or synthetic fatty acids that
4 are based on hydrogenation process.

5 Next. So as you look at the
6 kinds of studies that we examined in the last
7 10 years, because it was not addressed in the
8 last dietary guidelines, we went back to 2000,
9 we looked in those studies, as criteria from
10 two years of age to adults, and we looked at
11 various outcomes for includes criteria,
12 cardiovascular disease, metabolic syndrome,
13 and so forth, and the kinds of studies are
14 consistent with our original inclusion
15 criteria.

16 Again, the exclusion criteria were
17 the same as we did for all of our particular
18 charges. The health outcomes that we chose
19 were consistent with, we examined the entire
20 fatty acid scheme, that is, the biomarkers
21 associated with lack of protein levels. Next
22 slide.

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1 As we look at the evidence from
2 the last 10 years, interestingly enough, there
3 are only three studies, two of the studies
4 were RCTs, those two studies were positive,
5 and one systematic review was somewhat
6 negative.

7 And what's really important here
8 as we look at the overt, at face value, you
9 would say, well, looking at coronary heart
10 disease endpoints we show no difference
11 between the ruminant and industrial *trans*
12 fatty acid. However we have to examine this a
13 little bit more closely. And as we examine
14 this more closely we realize in fact the
15 levels of the ruminant *trans* fatty acids are
16 seven to 10 times what you and I would consume
17 in a normal diet. So let's look at the next
18 slide, please. And these are the three
19 studies that we examined. And in each case it
20 was the levels that we were looking at --
21 times the amount of *trans* fatty acids. These
22 are very carefully designed, carefully

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1 designed products, because these things do not
2 occur normally at this concentration. That
3 effect, we had to look at these outcomes. And
4 in each case we saw that while we had LDLs
5 increased in the Chardigny study, and the
6 small studies there, and we looked at the
7 other RCT study, Motard-Belanger. Again, the
8 LDLs tended to be higher. We also took a look
9 at the HDLs; HDLs tend to be lower. And yet
10 we look at the non-systematic reviews and look
11 at the variety of studies, and they seem to
12 corroborate that the effect on lipids and
13 *trans* fatty acids relative to the sources were
14 not differentiated, as in fact the most
15 significant difference.

16 So on the outside we would say
17 that there aren't any differences. Well,
18 let's take a look at what we might say next.
19 As we look at this conclusion, there is little
20 evidence for substantial biological
21 difference, of detrimental effects between the
22 two sources of fatty acids. However, the

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1 evidence does not suggest an appreciable
2 effect on health in ruminant *trans* fatty acids
3 on the average current intake by the
4 population of approximately .5 percent. That
5 is really critical. Those studies had doses
6 from about seven to 10 percent - excuse me -
7 about 5 percent of the energy level, which
8 obviously is 10 times what we would normally
9 consume. Based on those three kinds of
10 studies, including the meta-analysis, would
11 give us a Grade II.

12 Comments. Implications, here we
13 go. Clearly this is consistent with what we -
14 what it was last time we said in the dietary
15 guidelines that truly industrial *trans* fatty
16 acids should be eliminated. And clearly we
17 have seen that across the country and
18 throughout the food industry and baking
19 industry. Again because ruminant *trans* fatty
20 acid includes such a small amount of calories
21 that are unlikely to provide any effect in
22 terms of the clinical outcomes that were

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1 assessed, that is on serum lipids and
2 lipoproteins. And ruminant *trans* fatty acids,
3 normal constituents of dairy products and in
4 meat products, and therefore obviously a
5 complete removal of ruminant *trans* fatty acids
6 would obviously restrict the nutrient
7 contributions of these kinds of foods to the
8 total diet.

9 Recommendations: we certainly see
10 that - we would agree that more research in
11 this area is required to look at the impacts
12 of ruminant *trans* fatty acids relative to
13 industrial fatty acids relative to
14 cardiovascular disease or any other type of
15 chronic disease risk.

16 Comments?

17 DR. THOMAS PEARSON: Discussion?

18 No one here is surprised that they are
19 differentiated, Tom.

20 DR. FUKAGAWA: Can you hear me?

21 Can you hear me?

22 DR. THOMAS PEARSON: Yes, go

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1 ahead.

2 DR. FUKAGAWA: This is Naomi.
3 I'm having problems with sound. But since we
4 are saying that industrial *trans* should be
5 eliminated from the American diet, why would
6 we want to study it further?

7 DR. CLEMENS: We want to study it
8 further relative to the ruminant to see if in
9 fact even at the levels we recommend, Naomi,
10 would they have any impact. Right now the
11 data suggest that they would not have an
12 impact.

13 DR. FUKAGAWA: Industrial or
14 ruminant?

15 DR. CLEMENS: Ruminant.

16 DR. FUKAGAWA: Ruminant, oh you
17 mean testing ruminants at the level that we
18 are now consuming?

19 DR. CLEMENS: Yes. As you know a
20 lot of the data came out of Wisconsin, and you
21 may recall the data by Mike, and we need to
22 examine that. We certainly see that being

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1 used, Naomi, in a lot of livestock
2 applications, in terms of animal feed. What
3 happens in terms of when, those kind of
4 products we see, if they have any impact in
5 terms of our biomarkers in terms of
6 cardiovascular disease or any other types of
7 risk.

8 DR. FUKAGAWA: Okay.

9 DR. THOMAS PEARSON: Roger, if
10 the average --

11 DR. CLEMENS: And it is
12 complicated because there are so many isomers
13 of these naturally occurring *trans* fatty
14 acids.

15 DR. FUKAGAWA: Exactly, so is
16 that perhaps what one would want to
17 investigate?

18 DR. CLEMENS: I think at the end
19 of the day the answer would be yes.

20 DR. PI-SUNYER: Roger, even
21 though .5 percent is taken by the population
22 as a whole, are there a significant number of

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1 people who are very big meat eaters who would
2 get significantly more than this? And for
3 whom it might be a risk?

4 DR. CLEMENS: That is a really
5 good question, Xav. There was actually one
6 study that we looked at, it was at .7 percent
7 of the energy, and the conclusion of that
8 study indicated that there wasn't any apparent
9 risk at that level. Clearly to your point as
10 well, there may well be some outliers in the
11 general population. Yet for the general
12 population the .5 percent seems to be the
13 normal intake and consumption level, and
14 without any apparent risk.

15 DR. THOMAS PEARSON: Roger, I
16 think we need to move on. We have a few
17 modeling pieces, so let's move on to the food
18 pattern modeling. And we had three questions,
19 each of them very helpful, particularly in
20 discussing the implications of some of our
21 questions previously.

22 The first one talking about

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1 saturated fatty acid modeling, looking at the
2 impact of food choices and overall nutrient
3 adequacy, when you limit cholesterol-raising
4 fatty acids to less than 7 percent of total
5 calories and less than 5 percent of total
6 calories, cholesterol-raising fatty acids
7 here, operationalized as total saturated fatty
8 acids minus stearic acid. So stearic acids
9 are about 2 percent of calories in the diet.

10 And the food patterns that would
11 meet all of the nutritional goals within the
12 caloric limits obviously has to do with using
13 lean ground beef, low fat or fat-free cheeses,
14 and baked chicken without the skin.

15 The next slide shows the various
16 models, across a variety of calories and fatty
17 acid patterns that you see here that were
18 used in these models. Next. And the summary
19 from our modeling team is that the USDA food
20 patterns include foods only in nutrient-dense
21 forms without excess solid fats. So the small
22 amounts divided equally between calories from

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1 solid fats and calories from added sugars is
2 included. A small amount of discretionary
3 calories is available, therefore, with these
4 models, and the current patterns have 8 to 9
5 percent of calories from saturated fats and 6
6 - 7 percent of calories from cholesterol-
7 raising fats.

8 And basically the - if you are
9 going to then reduce cholesterol-raising fatty
10 acids further, you would have to replace all
11 solid fats isocalorically with oils, and you
12 could then lower cholesterol-raising fatty
13 acids further to 5 - 5.5 percent of calories
14 and total saturated fats reduced to 7 percent.

15 So just to give an idea of the modelings
16 within the nutritionally adequate ranges.

17 Why don't we move on to the
18 cholesterol modeling, and we'll take all the
19 modeling at the end here. What we also had
20 was looking at food choices and nutrient
21 adequacy if you were to limit dietary
22 cholesterol to less than 200 milligrams a day.

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1 Again this is some recommendations for a
2 high-risk patients with coronary disease,
3 hypolipidemia obviously has this
4 recommendation.

5 Here you can see the methods that
6 were used. The amount of cholesterol at the
7 base food patterns in each calorie level; the
8 amounts of cholesterol in each food group,
9 then selecting the foods to modify, revising
10 the amounts in the food groups to reduce the
11 cholesterol, identify levels of cholesterol
12 and calories in the revised food patterns.
13 And looking at what nutrients changed and what
14 didn't change, and which nutrient goals were
15 met or not met.

16 And the next slide is just the
17 calorie levels again with the energy and
18 cholesterol contents with each of the
19 patterns. And the USDA food patterns then
20 includes only nutrient dense forms without
21 excess solid fats. And across those caloric
22 patterns from - that raises from 92 at 1,000

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1 to 290 at 3,200 calories per day, and
2 therefore cholesterol levels can be reduced to
3 less than 200 milligrams per day by limited
4 eggs to less than two per week; reducing meats
5 and poultry; and substituting some oils for
6 solid fats.

7 So certainly the suggestion is
8 that this would be doable. If you give them
9 that there would be reductions in protein;
10 also choline. I might see even at the
11 baseline that this did not meet the allowance
12 recommendations from the IOM. Also Vitamin A
13 and Vitamin D, the fat soluble vitamins, would
14 be reduced, and EPA and DHA. Those same
15 changes would increase Vitamin E with the
16 increased oils in nuts, which would still be
17 below the RDA for most foods.

18 So I think the point with choline
19 and Vitamin D, they are below the recommended
20 levels to begin with, and this would take them
21 even lower. So a diet can be constructed at
22 less than 200 milligrams per day of

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1 cholesterol. The low cholesterol diet would
2 have further reductions in several nutrients,
3 particularly choline, vitamin D. And the
4 restrictions in cholesterol intake to less
5 than 200 milligrams per day should target
6 subgroups at high risk of cardiovascular
7 disease or type 2 diabetes, given the limited
8 general population data on benefits.

9 Okay, and Roger, do you want to
10 talk about the seafood modeling?

11 DR. RIMM: I think it's me.
12 Eric.

13 DR. THOMAS PEARSON: I'm sorry,
14 right.

15 DR. RIMM: So this is another
16 what-if scenario given the fact that we think
17 there is strong evidence to suggest that 250
18 milligrams per day of n-3 fatty acids is
19 beneficial. We wanted to look at what is the
20 impact on nutrient adequacy of increasing
21 seafood in the USDA food patterns data. And
22 we had three scenarios.

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1 And thanks to several of the staff
2 including Kelly for bringing together the food
3 safety people with the fatty acids people with
4 a few other groups to look at this. And here
5 are the three patterns we looked at, where
6 four ounces per week of seafood high in n-3
7 fatty acids, that's EPA and DHA, so call it
8 the HI3 group.

9 And what happens if you have 8
10 ounces per week of seafood, including seafood
11 both in a low n-3 and high n-3 classes? And
12 in this we looked at the distribution based
13 on NHANES data, and we used that same
14 proportion. So assuming that people had 8
15 ounces per week, or two servings per week of
16 low and high n-3 fatty acids.

17 And our final choice was, what if
18 individuals had 12 ounces per week of seafood
19 low in n-3 fatty acids? So that is three
20 servings per week. Ironically we're coming
21 upon lunch, so I'm sure we are all hungry.

22 For this we used amounts of

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1 seafood and the USDA food patterns were
2 increased at four, eight and 12 ounces using
3 the 2000-calorie reference level by
4 substituting for meat and poultry. So four
5 ounces of HI3, all the seafood is HI3, and low
6 three fish is set to zero.

7 For the second scenario, 8 ounces
8 of L03 and HI3, using the current ratio of L03
9 to HI3 in the population.

10 The third scenario is 12 ounces of
11 L03. All seafood is L03, and HI3 is set to
12 zero. The amounts of eggs, nuts, seeds and
13 soy products are held constant. And the
14 amounts of solid fats in the patterns were not
15 modified either. Next slide, please.

16 So the amounts of food subgroups
17 in patterns adjusted using the same
18 proportions as in the 2000 kcal patterns. And
19 we then assessed the nutrient adequacy of food
20 patterns, compared to the RDAs from the IOM
21 report of 2006, and there is no RDA for EPA or
22 DHA, so the amounts were compared to base

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1 patterns. Next slide.

2 And you can see here there are
3 several different scenarios. The first column
4 is the base USDA pattern, and then we have the
5 servings of meat, poultry, high-fish, low-
6 fish, eggs, soy products, nuts and seeds, and
7 then there is a total at the bottom.

8 And each column then -- columns
9 two, three and four, are what happens when we
10 substituted the seafood at the three different
11 levels. And you can see the ounce equivalents
12 per day for each of these. So meat went down
13 a little for column one, more so for two and
14 three. Same for poultry. And then you can
15 see the other things are not changed. Eggs,
16 soy, nuts and seeds are not changed. So
17 overall at the bottom you get the same ounce
18 equivalence. It's just that we are consuming
19 more fish that has differing levels of n-3
20 fatty acids.

21 Next slide. So what results of
22 this found is that we didn't get substantial

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1 change in energy, protein, carbohydrates, or
2 total fat, nor was there substantial changes
3 in cholesterol, saturated fat, MUFUs and
4 PUFAs.

5 We did, because fish contain
6 selenium, vitamin D, and B-12, we do get a
7 slight increase in those metals and
8 micronutrients. Next. So overall for the
9 seafood modeling summary, the amounts of
10 seafood in the USDA food patterns could be
11 increased to the levels specified without any
12 negative impact on nutrient adequacy, and
13 overall using these patterns what we've found
14 is that we would achieve that level of DHA
15 plus EPA per day of 296 milligrams in the
16 high-3 group; on average we have 259
17 milligrams in the middle group; and even those
18 people who had three servings of low-3 fish
19 we would achieve the levels of 250 milligrams
20 per day EPA and DHA. Next.

21 Ah, yes, so for this particular
22 analysis we did not include methyl mercury.

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1 Contaminants are not part of the NHANES
2 nutrient composition database, so we are going
3 to have to rely on Rafael's report on that.
4 The seafood species of interest could not be
5 identified, and the amounts of these species
6 in the patterns were estimated to come to the
7 low-3 fish and the high-3 fish. And of course
8 the analysis did not address vegetarian diets.

9 That would take a bit more work and be
10 focused on the vegetable sources of n-3 fatty
11 acids. And I believe that is it. Are there
12 any questions for any of us?

13 DR. THOMAS PEARSON: And the
14 modeling questions, open for brief discussion?

15 Okay. I think we are a little bit
16 past our time. I want to thank everybody for
17 their good comments and lively discussion, and
18 I think we can turn this back to Linda.

19 DR. VAN HORN: Excellent job,
20 Tom, Eric, and your whole group; that was
21 really wonderful. And I suspect that
22 discussion was just halted by the confluence

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1 of peoples' stomachs at this point. I'm sure
2 there will be more discussion, but it was
3 great to hear and see the deliberations of
4 your group. Really excellent.

5 So with that I just want to thank
6 everyone for your patience thus far. We are
7 now ready to take our lunch break, and we will
8 return in one hour. We are supposed to start
9 again at 2:15 Eastern time. So please be back
10 by then. Thank you.

11 (Whereupon, at 1:25 p.m., the
12 proceedings in the above-entitled matter went
13 off the record and returned at 2:18 p.m.)

14 DR. FUKAGAWA: In the interest of
15 time, I'd like to just launch into the next
16 reports from the Energy subcommittee that was
17 chaired by Dr. Xavier Pi-Sunyer.

18 Xav?

19 ENERGY BALANCE SUBCOMMITTEE

20 DR. PI-SUNYER: Yes, hello. So
21 we are going to divide this presentation, and
22 each of us on the subcommittee is going to

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1 take a different portion of it. I think what
2 we should do in the interest of time is let
3 whoever is talking go through all of their
4 questions, and then we'll open it up for
5 questions after each - at the end of each
6 speaker, but not in the middle of it.

7 These are the questions that we've
8 addressed. And the first one is, what effects
9 do the food environment and dietary behaviors
10 have on body weight? And the chair of that
11 particular question was Miriam Nelson, and she
12 will come on now to discuss that question.

13 Mim.

14 DR. NELSON: Sure, thank you. So
15 this is the series of questions that we are
16 going to be addressing today are ones that we
17 haven't addressed before, so it complements
18 the full chapter.

19 So my charge, working with the
20 very able USDA staff, Eve and Julia and
21 others, was to look at the food environment,
22 body weight and we put in vegetable and fruit

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1 intake here although the main focus is on body
2 weight, but this came out of the review.

3 So a little, just a tiny bit of
4 background. As we all know the overall food
5 environment has changed. There are many more
6 places to buy and consume food. And in fact
7 the number of commercial eating places has
8 gone up about 90 percent since 1972. The
9 number of fast food restaurants has gone up by
10 147 percent. The percentage of meals eaten
11 away from home is about 150 percent up. So
12 things have really changed. There is less
13 availability of healthy foods in urban and low
14 income areas, the so-called food deserts.
15 Foods are consumed in a variety of different
16 places, and the food supply is quite
17 different, and we've spoken about that in many
18 of the other sessions.

19 But increased availability of
20 calories, sweeteners, refined grains,
21 processed vegetables and fruits, cheese and
22 chicken, those are the things that have really

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1 increased, with a decrease in fluid milk, and
2 fresh vegetables and fruit. Next slide.

3 So for the environment the
4 proposed conclusion is with a Grade of II for
5 BMI and a Grade of II (moderate) for vegetable
6 and fruit intake around the food environment.

7 There is substantial evidence that indicates
8 that the food environment is associated with
9 dietary intake, especially less consumption of
10 vegetables and fruits and higher body weight.

11 Availability of healthy foods including
12 vegetables and fruits is associated with
13 improved dietary intake and weight status,
14 especially in economically disadvantaged
15 areas. The presence of supermarkets and other
16 sources of fruits and vegetables is associated
17 with lower BMI, while lack of supermarkets and
18 long distances to supermarkets is associated
19 with higher BMI, and increased density of fast
20 food restaurants and convenience stores is
21 related to increased BMI, and this last
22 sentence is, stronger relationships tend to be

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1 seen between the environment and vegetable and
2 fruit intake than with body weight. It's more
3 - it's not - it's just that we have a few more
4 studies, not that there is a stronger
5 relationship; I just wanted to clarify that.

6 And fast food is defined as foods
7 designed for ready availability, use and
8 consumption, and sold at eating establishments
9 for quick and available -- availability and
10 take out. So the implication of the
11 environment and food question is that policy
12 and private sector efforts must be made to
13 increase the availability of healthy foods for
14 all Americans, especially low income
15 Americans, so greater access to grocery
16 stores, produce trucks, farmers' markets, and
17 greater financial incentives to purchase and
18 prepare healthy foods, as the healthier foods
19 tend to be more expensive than the cheap and
20 processed foods.

21 Next slide. We looked at for -
22 with the NEL we only reviewed systematic

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1 reviews. We didn't go back to the original
2 literature as there was enough to look at
3 here. All 10 studies found a relationship
4 between the environment and body weight and
5 dietary intake. Three found neighborhood-
6 level measures of economic disadvantage were
7 associated with obesity and poor dietary
8 intake. Eight reviews found that the
9 availability of healthy food or lack thereof -
10 - supermarkets, vegetable gardens -- is
11 associated with weight status and dietary
12 intake, especially fruit and vegetable intake,
13 and two reviews found that higher density of
14 fast - systematic reviews found a higher
15 density of fast food restaurants and
16 convenience stores in association with higher
17 rates of obesity.

18 So I think this is very much in
19 line with what we expected to see. We didn't
20 dive all that much deeper into things like
21 sidewalks and some other sort of built
22 environment questions. It was more around

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1 food availability and food environment that we
2 looked at, and we kept it at a fairly high
3 level for this first time, because this hasn't
4 been reviewed yet by the Dietary Guideline.
5 Next slide.

6 So then turning towards behaviors
7 - if I could go back to the last slide just
8 for a second, the only thing I would say is
9 that in the Integration and Translation
10 chapter, we - a fair amount of this work will
11 be considered in that chapter just because it
12 seems to be when you think of the sort of
13 systems-related aspect of food availability
14 both on the negative and the positive, that is
15 where we need to be focusing on, a lot more
16 than just individual behavior change. But
17 moving on to behavior, looking at it in both
18 children and adults, we looked at a number of
19 different behaviors related to body weight,
20 and many of these were also addressed in the
21 2005 Guidelines, and so we've updated the
22 review, but looking at eating out, portion

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1 sizes, screen time, breakfast consumption,
2 snacking, eating frequency, and diet self-
3 monitoring.

4 We focused on 2000 to present,
5 children two to 18 and adults 19 and up, and
6 we excluded cross-sectional studies.

7 The proposed conclusion for what
8 is the relationship between eating out and
9 body weight, we proposed that this is a Grade
10 I (strong) evidence, there is strong and
11 consistent evidence that children and adults
12 who eat fast food are at increased risk for
13 weight gain, overweight and obesity, the
14 strongest relationship between fast food and
15 obesity is seen when one or more fast food
16 meals are consumed per week. There was not
17 enough evidence at this time to evaluate
18 whether eating out at other restaurants and
19 the relationship between risk of weight gain
20 and overweight and obesity, so it was focused
21 mostly -- exclusively on fast food
22 restaurants.

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1 The proposed implication is that
2 if people do choose to eat fast food they are
3 encouraged to choose lower calorie options and
4 smaller portions. The restaurant industry is
5 also encouraged to offer healthier foods in
6 appropriate portion sizes that are low in
7 calories, added sugar and solid fat.

8 Looking at the evidence, these
9 were - there was one systematic review and
10 several prospective cohort studies. This is
11 not a topic that I think is possible at this
12 point in time to look at an RCT, because this
13 is really a relationship with body weight at
14 the moment, and I think there are some issues
15 with a number of these behavior and
16 environment questions, with the design, and I
17 think that this is what we are going to have
18 to be looking at.

19 And then there were several
20 prospective cohort studies, of which, all were
21 strong in terms of relationship with the
22 exception of one that was a negative

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1 association with girls and no association with
2 boys. But all the other studies were very
3 strong. Next.

4 With adults, similarly the
5 systematic review plus the prospective cohort
6 studies, with the exception of one, which was
7 positive for fast food, but there was no
8 relationship with other restaurant food; all
9 were strong and positive. Next slide.

10 What is the relationship between
11 portion size and body weight? And this has
12 been - this is more just an update of the 2005
13 DGAC. The proposed conclusion is that there
14 is strong evidence there's a positive
15 relationship between larger portion sizes and
16 body weight. The conclusion from 2005 is "the
17 amount of food offered to a person influences
18 how much he or she eats, and, in general, more
19 calories are consumed when a large portion is
20 served rather than a small one."

21 The proposed implication is that
22 individuals are encouraged to prepare, serve

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1 and consume smaller portions at home, and to
2 choose smaller portions of food while eating
3 foods away from home. Next slide.

4 These are the studies that we
5 looked at. There were a number of RCTs, and
6 there were no studies in children, because we
7 didn't focus on weight loss. It was more on
8 weight maintenance over time, and one case-
9 control study.

10 So what is the relationship
11 between screen time and body weight? This is
12 also Grade I, and this is also an update from
13 2005. There is strong and consistent evidence
14 in both children and adults that screen time
15 is associated with increased overweight and
16 obesity. The strongest association is with
17 television screen time. And the proposed
18 implication is that children and adults should
19 limit screen time, especially, here we are
20 sitting for 14 hours over the next two days
21 watching our screens, but children and adults
22 should limit screen time, especially

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1 television viewing, and to not eat food while
2 watching television. We propose in terms of
3 the implication to support the American
4 Academy of Pediatrics guideline of no more
5 than one to two hours of total media time for
6 children and adolescents. And to discourage
7 television viewing for children less than two
8 years of age, and then to also support the
9 Healthy People 2010 objective to increase the
10 proportion of adolescents who view television
11 two or fewer hours on a school day. So we
12 propose to use those as implications to be in
13 concert with other guidelines. Next slide.

14 With this update these are a
15 number of - there is a meta-analysis we looked
16 at for children. We didn't do a full NEL
17 search, and there was a positive relationship
18 between screen time and adiposity, and in
19 adults, with the update you can see there are
20 eight cohort, prospective cohort studies all
21 with a strong relationship between screen time
22 and weight. I don't think any of this is very

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1 new; it was more of an update for the
2 literature. Next slide.

3 What is the relationship between
4 breakfast consumption and body weight? And I
5 will say that we have been working, and it
6 will be presented tomorrow to coordinate this
7 question with the Nutrient Adequacy
8 subcommittee. And I would say at the moment
9 there is a Grade II (moderate) for children,
10 Grade III (limited) for adults. There is
11 modest evidence that children who do not eat
12 breakfast are at increased risk for overweight
13 and obesity. The evidence is stronger for
14 adolescents. There is inconsistent evidence
15 both for the positive and the negative for
16 adults who skip breakfast, that it puts them
17 at increased risk for overweight and obesity,
18 and I think a fairly simple, straightforward
19 proposed implication is that children and
20 adults are encouraged to consume a nutrient-
21 dense breakfast, and we will be defining
22 nutrient-dense much more tomorrow. Next

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1 slide.

2 You can see this is for children.

3 You can see that, so a negative relationship
4 is that it means - a positive one is that it
5 puts them at risk for overweight and obesity,
6 so a negative is in the right direction. You
7 can see that with an RCT, breakfast
8 consumption only with nutrition education was
9 positive. Eve, are you on the call here? I'm
10 thinking actually the positive here, or Julie
11 are you on the call? Because I think there is
12 - this positive, this study, the positive
13 actually is in the direction we would want,
14 correct?

15 DR. OBBAGY: No, the negative.
16 So if you increase your breakfast. Yes, you
17 want the inverse in this case.

18 DR. NELSON: We want the inverse
19 in this case. So positive means a
20 relationship with more breakfast, more
21 obesity, or not?

22 DR. PI-SUNYER: No.

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1 DR. OBBAGY: The positive is if
2 you increase your breakfast intake you
3 increase your body weight, whereas the
4 negative is if you increase breakfast intake
5 you decrease body weight.

6 DR. NELSON: Body weight. So
7 here breakfast is associated with an increase
8 in body weight with the Rosado study. I
9 thought the nutrition education actually
10 reduced obesity rates. In the Rosado.

11 DR. PI-SUNYER: Yes, these are
12 reduced.

13 DR. OBBAGY: I think that first
14 one is supposed to be a negative association.

15 DR. NELSON: I think it is too.
16 I think that is a typo, because otherwise they
17 are not in concert, and that was why I was -
18 okay. So that should be a negative, because
19 it was only with nutrition education where
20 they saw a decrease in body weight. Then you
21 can see with these other trials there was
22 either no association or there was a

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1 association the way we would expect with
2 breakfast being protective of body weight.

3 And a couple of these studies show
4 differences between girls and boys, but it's
5 not universal here, and that's why I gave it a
6 Grade II. Next slide.

7 With adults, there was also a
8 negative relationship in the direction that we
9 had expected, although one study didn't show -
10 it's just that there weren't as many studies
11 here in adults as there were in children.

12 Next slide. In terms of
13 snacking, this was a real nightmare, because
14 of - if you actually I think the NEL search
15 was very difficult to do with this, because
16 all the different studies actually define
17 snacking in a different way. I'm happy that
18 there is a new study, large study, looking at
19 snacking trends over time since the '70s to
20 now, done out of UNC. It has done more
21 definition of what snacking is, and I think
22 that that will be a help for the literature,

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1 so at the moment I think mostly because of the
2 methodology, there is inconsistent evidence to
3 suggest that snacking is associated with
4 increased body weight, and I think the reason
5 is the inconsistency in the variability in
6 design and definitions for snacking. I think
7 that it's fine to have a proposed implication
8 that when snacking, Americans are encouraged
9 to choose foods that help meet their nutrient
10 needs while staying within calorie limits.
11 Next slide.

12 Here, so it's a little complicated
13 because there's also with television viewing,
14 but three found a positive relationship
15 between snacking and adiposity, one only found
16 the positive relationship in front of the
17 television, and three didn't find a
18 relationship between snacking and adiposity.
19 So there is really quite a variability here,
20 so I just think it's inconsistent at the
21 moment. Next slide.

22 With adults, two studies found a

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1 positive relationship, but we only have two
2 studies, so I think we have insufficient data
3 at this point, although it seems like there is
4 a positive relationship. Next slide.

5 So what is the relationship? If
6 snacking was difficult to look at, this one
7 was even more difficult, which is, what is the
8 relationship between eating frequency and body
9 weight? Here, I think there is limited
10 evidence, or insufficient evidence, that
11 frequency of eating has an effect on
12 overweight and obesity in children and adults.

13 Some of this also was methodologically very
14 difficult to feather out in terms of is this
15 in addition to three meals a day, or is it
16 with all meals in the day? There is still
17 some definitions that need to be determined,
18 and the implication is that children and
19 adults are encouraged to follow a frequency of
20 eating that provides nutrient-dense foods
21 throughout the day. Caution must be taken
22 that the frequency of eating helps children

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1 and adults stay within daily caloric
2 requirements. I will say for the snacking,
3 breakfast and body weight questions, or
4 rather, and frequency of eating, we did not
5 look at - we didn't include weight loss
6 studies. These were all in terms of
7 relationship with body weight or weight
8 maintenance over time. I should clarify that.

9 So, in children, there was one
10 prospective study that showed a negative
11 relationship between eating frequency and
12 adiposity in girls, and in adults there was a
13 positive. So I just don't think we have
14 enough data to say much about this at the
15 moment. Next slide.

16 The only place that we did look at
17 weight loss and weight control was in people
18 in terms of self-monitoring, and here this is
19 an update from 2005 and some other reports
20 that there is a strong evidence that for
21 adults who need or desire to lose weight or
22 who are maintaining body weight following

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1 weight loss, that self-monitoring of food
2 intake improves outcomes. So adults are
3 encouraged to self-monitor food intake to
4 improve outcomes when actively losing weight
5 or maintaining body weight following weight
6 loss, and in addition there is also evidence
7 that self-monitoring of body weight and
8 physical activity improves outcomes, when
9 actively losing weight or maintaining body
10 weight following loss.

11 Here are the trials. So this is,
12 positive is that they had better outcomes. So
13 there are quite a few RCTs of which only one
14 RCT did not show an improvement; the others
15 showed an improvement. I will mention that
16 several of these were studies done overseas,
17 but this just adds to the literature of
18 studies that have been done in the past. Next
19 slide.

20 So research recommendations: more
21 research is needed to understand both positive
22 and negative environmental influences that

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1 affect body weight, and how change in the
2 environment impacts dietary intake and health
3 outcomes and body weight. This is a very new
4 field, and I think it deserves a lot more good
5 research. Macro level research on the effects
6 of local and national food systems on dietary
7 intake and health outcomes is necessary to
8 better understand the relative contributions
9 of different sectors on dietary intake and
10 health.

11 More research on the influence of
12 snacking and meal frequency on body weight and
13 obesity is needed. Better definitions for
14 snacking will need to be developed, and I
15 believe they are being. Research is needed on
16 how best to influence fast food and restaurant
17 manufacturers and retailers to reduce portion
18 sizes and to improve the quality of food.

19 And I might also add, and how we
20 can also influence consumers' choices within
21 those establishments. And then more research
22 is needed on other behaviors that might

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1 influence eating practices such as child
2 feeding practices and other family influences
3 and peer influences.

4 And I think that might be my last
5 slide. Is that correct?

6 DR. PI-SUNYER: That is correct.

7 So questions for Mim?

8 DR. NELSON: I know that was a
9 lot, but I know we have a lot to cover today.

10 DR. APPEL: This is Larry. First
11 of all, that was terrific. I learned a lot
12 myself. But the fast food. I think this
13 could become a lightning rod. These are all
14 observational studies. Were they able to
15 control for other aspects, either at the
16 neighborhood or individual level, related to
17 like SES or income or these other factors that
18 people will probably argue are more important
19 than the fast foods?

20 DR. NELSON: Yes, they all - I'd
21 have to go back and look at each of the
22 individual studies, but most of them really

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1 did control for income and SES, education. I
2 must say, when we were looking at that, that
3 we were surprised at the strength of the
4 relationship and the consistency in both
5 adults and children. We weren't expecting
6 that. And there were quite a few trials - not
7 trials but prospective studies - in which the
8 design was really strong. Eve and Julie were
9 really helpful with this. And we really,
10 because we are aware that this could be a
11 lightning rod. But the strength of the
12 relationship was pretty strong. And then,
13 again we also we saw it on the flip side when
14 we looked at the food environment and its
15 relationship, because we saw it two different
16 ways, when we looked at the food environment,
17 the number of fast food restaurants in an area
18 was also related to obesity rates. So it was
19 supportive in both directions.

20 DR. APPEL: I think you should
21 actually mention that, because I think it is
22 going to come up.

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1 DR. NELSON: Yes, I think - I'm
2 going to make a note of that.

3 DR. RIMM: Mim, this is Eric
4 Rimm. Can I pile on there? I think this
5 really is spectacular, and I too learned lots.
6 And I wonder, can we take your first two
7 conclusions and sort of merge them? If the
8 number of fast food restaurants are associated
9 with obesity in a given population, can we say
10 that is also the case for kids? It seems like
11 your second conclusion was that fast food
12 restaurants cause obesity. And an implication
13 of this is that fast food restaurants
14 shouldn't be allowed to be in high-density, in
15 places where there are a lot of kids, like in
16 schools or around schools. Is that a
17 potential implication of your first two
18 conclusions?

19 DR. NELSON: I think it is. I
20 think it is. I think that different towns
21 zone differently, but I think that could be an
22 implication. I'm making a note of that as

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1 well.

2 DR. RIMM: I know there are some
3 progressive cities that do this, but this
4 would be a fantastic implication if we really
5 think that is a cause of obesity in kids.

6 DR. NELSON: Well, a contributor.

7 DR. RIMM: Sorry.

8 DR. NELSON: But I'm not sure
9 that we can merge the two. I think in the
10 discussion and the chapter we can make note of
11 that.

12 Let's go with other questions and
13 I can come back to my thought.

14 DR. PI-SUNYER: Any other
15 questions for Mim?

16 DR. APPEL: This is Larry again.
17 The diet self-monitoring, is this a - I
18 wasn't quite sure - is this a calorie measure,
19 assessment? I am just wondering if you need
20 to be a little more specific.

21 DR. NELSON: They did it in a
22 variety of ways. It wasn't just calories. It

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1 was also just monitoring the different
2 studies, not all did it the same. It was
3 just monitoring food intake, size - they were
4 done in a couple of different ways. But let
5 me also take a look closer at that which may
6 have been the strongest.

7 DR. APPEL: Because I think it's
8 a little bit vague when you say food
9 monitoring. I mean, at least in contemporary
10 trials, they are really trying to either
11 correctly measure calories or to measure
12 indirectly calories by proxy. So I would
13 actually, if you feel comfortable, I would add
14 calories to that.

15 DR. NELSON: Yes, I'm comfortable
16 doing that. Eve or Julie, if you could make
17 note of that, and I will make note of that as
18 well. But we will add calories. What I was
19 going to add is that actually with Eve and
20 Julie and Trish were very helpful - what I
21 haven't presented because we don't have time
22 is, we actually have a fairly detailed

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1 historical look at the change in the food
2 environment from the 1970s to current in terms
3 of eating establishments, portion sizes, just
4 sort of how things have changed, and I think
5 that will be helpful as sort of the basis for
6 the whole report, because it shows the
7 historical perspective, not just what we are
8 eating right now. And that will help to set
9 up these massive changes in the food
10 environment that have happened.

11 DR. NICKOLS-RICHARDSON: This is
12 Shelly. And just to add to what Larry talked
13 about before, the Food Away From Home report
14 that was published in February 2010 by the ERS
15 they, in their estimation approach, count some
16 of the things like food preferences,
17 knowledge, time constraints, so forth, and
18 there are a couple of quotes from this report,
19 quote: "For the average consumer eating one
20 meal away from home each week translates
21 directly to two extra pounds per year." And
22 then the other quote that I think is pretty

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1 striking is that one additional meal eaten
2 away from home increases daily intake by about
3 134 calories.

4 So if there is a way to
5 incorporate their report into the text and the
6 background, I think obviously they have done a
7 good job and it would be important to include
8 that.

9 DR. NELSON: Yes, and that is
10 part of the sort of background that we've got.

11 But those two quotes we can add.

12 DR. FUKAGAWA: This is Naomi.
13 Also look at differences in, sort of,
14 socioeconomic - I may have missed that.

15 DR. NELSON: Well, it did come
16 out as a factor. And it's in the proposed
17 conclusion. It keeps coming out. And I think
18 what we need to do, and this will come also
19 up, even more so in the Integration and
20 Translation chapter, as we proposed in the
21 environment conclusion or implication is that
22 we need to have greater financial incentives,

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1 or figure out a price structure for the
2 healthier foods to be cheaper than the non-
3 healthier foods, however we want to define
4 them, and because the socioeconomic piece
5 keeps coming up.

6 DR. FUKAGAWA: That doesn't get
7 broken down into ethnic or cultural --

8 DR. NELSON: Not at the moment.

9 DR. FUKAGAWA: Okay.

10 DR. PI-SUNYER: Any other
11 questions for Mim?

12 DR. SLAVIN: This is Joanne. I
13 have a question about the breakfast in adults.

14 This is very consistent for a Grade III. Was
15 that just because of the number of studies?

16 DR. NELSON: Yes. It was the
17 number and I believe it was primarily the
18 number of studies that we just didn't feel
19 like there was enough there. And I think I
20 can - while the next presenter is presenting I
21 can just dig into that a little bit and maybe
22 come back and answer that question. Would

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1 that be helpful?

2 DR. SLAVIN: That would be great,
3 thanks.

4 DR. PI-SUNYER: Okay, let's move
5 on to breastfeeding and maternal and
6 postpartum weight reduction -- retention. And
7 Rafael Perez-Escamilla is going to talk about
8 that.

9 DR. PEREZ-ESCAMILLA: Hello, good
10 afternoon.

11 The question that I will be
12 addressing is what is the relationship between
13 breastfeeding and maternal weight change, a
14 question that was not addressed in the 2005
15 report.

16 The NEL search strategy was based
17 on identifying literature reviews addressing
18 this question published between 2000 and 2010.

19 The Committee's proposed
20 conclusion is that breastfeeding may be
21 associated with moderate maternal postpartum
22 weight loss, and we assigned this a Grade II

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1 even though it is based on two randomized
2 controlled trials and several prospective
3 studies. Several of them did not control for
4 key confounders or had enough statistical
5 power.

6 It is important to note that
7 weight loss associated with breastfeeding is
8 small, transient and depends on breastfeeding
9 intensity and duration. As discussed later on
10 in this presentation, implications of these
11 findings for women in the U.S. need to take
12 into account that only a third of them are
13 breastfeeding extensively at three months
14 postpartum when the recommendation is for
15 women to breastfeed exclusively for six
16 months, endorsed by both the World Health
17 Organization and the American Academy of
18 Pediatrics.

19 Lactation increases energy
20 demands, but at the same time it increases
21 appetite substantially, without evidence that
22 lactation increases levels of physical

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1 activity. For this reason it is important to
2 establish the net effect of lactation on
3 maternal postpartum weight loss.

4 The Committee initially identified
5 four reviews, but based its conclusions mostly
6 on the reviews by Dewey and the Agency for
7 Health Care Research and Quality, or AHRQ.
8 This is because the AHRQ review builds upon on
9 the Fraser review, and the Kramer review only
10 discussed two randomized controlled trials
11 also addressed by Dewey in her review.

12 Dewey based her review on 15
13 studies, two randomized controlled trials
14 conducted in Honduras by her group, showing
15 that exclusive breastfeeding for six months
16 vis-à-vis four months led to greater weight
17 loss between four and six months postpartum.

18 In one of the trials the weight
19 loss was of -0.6 kg, and in the second one it
20 was -0.2 kg. The difference in weight loss
21 across trials was explained by the between-
22 group differences in breast milk energy output

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1 among women participating in both studies.

2 Dewey classified the 13
3 prospective studies that met the initial
4 inclusion criteria into those that actually
5 measured versus those that estimated weight
6 changes. Six out of the seven studies that
7 had the best methodology found an inverse
8 association between breastfeeding and
9 postpartum weight change. By contrast only
10 one out of the six studies with poor
11 methodology detected the association.

12 Here we concluded that there is a
13 dose/response relationship between
14 breastfeeding duration or intensity and
15 postpartum weight loss, and that weight loss
16 differences attributed to breastfeeding were
17 transient, being more evident between three
18 and six months postpartum, and she also
19 identified the need to improve study design in
20 future studies, especially the need to control
21 for key confounders and improve the clarity of
22 breastfeeding definitions used.

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1 AHRQ identified eight prospective
2 studies that met their inclusion criteria,
3 most of which were published after the review
4 by Dewey. From three studies that examined
5 return to pre-pregnancy weight, one found that
6 exclusive breastfeeding was not associated
7 with weight retention at one to two years
8 postpartum.

9 A second study found that
10 breastfeeding at one year was associated with
11 -1.2 kg of weight retention versus +2 kg of
12 weight retention among formula-feeding women
13 at one year postpartum.

14 A third study found that
15 breastfeeding was associated with reaching
16 pre-pregnancy weight six months earlier vis-à-
17 vis formula-feeding. However, consistent with
18 the weight loss associated with intensive
19 proceedings, and reported by Dewey, two
20 prospective studies found that postpartum
21 weight change was inversely associated with
22 breastfeeding intensity and duration.

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1 The remaining three studies that
2 classified women according to different infant
3 feeding categories did not find significant
4 between-group differences in total postpartum
5 weight changes. However, consistent with the
6 conclusion from Dewey, one study did find more
7 rapid weight loss between three and six months
8 postpartum among exclusively breastfed women.

9 The AHRQ review concluded that the effect of
10 breastfeeding on postpartum weight loss is
11 unclear, and that if an association was
12 present, the effect size is likely to be
13 small. They also make the very important
14 point that postpartum weight changes vary
15 enormously among women. And you can see the
16 range, how huge it is, just from one of the
17 studies conducted by Ohlin and Rossner.

18 So, future studies need in
19 addition to control for key confounders to
20 ensure that they are adequately powered to
21 detect the relatively small differences in
22 weight changes that have been found to be

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1 associated with breastfeeding.

2 In sum, the evidence supports the
3 conclusion that breastfeeding may be
4 associated with moderate maternal postpartum
5 weight loss. This relatively small effect is
6 linked with breastfeeding intensity.

7 And lastly given the very low rate
8 of exclusive breastfeeding and short
9 breastfeeding durations among women in the
10 U.S., the Committee does not recommend simply
11 issuing a blanket statement advertising
12 breastfeeding as an effective tool for
13 maternal weight loss among women in the U.S.

14 And that's the last slide.

15 DR. PI-SUNYER: Okay, thank you
16 very much, Rafael. Questions for Rafael?

17 DR. VAN HORN: Rafael, this is
18 Linda, can you hear me?

19 DR. PEREZ-ESCAMILLA: Yes, I can.

20 DR. VAN HORN: That was
21 excellent. Wonderful job. In our interest in
22 looking for ways to prevent obesity starting

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1 in childhood, are there data yet to document
2 offspring and any benefit in terms of weight
3 and weight gain in children of breastfeeding
4 mothers?

5 DR. PEREZ-ESCAMILLA: The evidence
6 is mixed, about 80 percent of cross-sectional
7 studies have found an association between
8 breastfeeding and less likelihood of childhood
9 obesity, and also several retrospective
10 studies. However, the randomized trial
11 conducted in Belarus, and the [inaudible]
12 trial by Kramer and colleagues does not
13 confirm that finding, and there is now another
14 prospective study that does not confirm the
15 findings. So I would say the jury is still
16 out regarding that point.

17 DR. VAN HORN: Okay, thank you.

18 DR. PI-SUNYER: Any other
19 questions for Rafael?

20 DR. NELSON: No, but this is - we
21 will keep going with Rafael - I had a 30-
22 second update on breakfast consumption.

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1 DR. PI-SUNYER: Okay, let's
2 finish with Rafael. Any other questions for
3 Rafael?

4 Okay, well, thank you, Rafael.
5 Go ahead, Mim.

6 DR. NELSON: Okay, so there were
7 seven trials for the breakfast consumption in
8 adults, one trial but it was with freshmen,
9 college age, that the more breakfast they ate
10 the greater weight gain, so that might be a
11 little tricky one to look at. And then four
12 out of the seven did show reduction in body
13 weight with breakfast consumption or
14 relationship with lower body weight. Then the
15 other two didn't show any association. So
16 it's kind of mixed, and so that's why it was a
17 Grade III as opposed to a Grade II. But I'm
18 happy to change that grade if people - four do
19 show a relationship with breakfast consumption
20 and lower body weight. It was just that one
21 showed a higher, but it was freshman young
22 adults, and two didn't show an association, so

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1 that was the reason for Grade III. But
2 suggestions?

3 DR. SLAVIN: I'm not sure in
4 Nutrient Adequacy, Shelly, we did, I'm trying
5 to think if there is any overlap with other
6 committees on breakfast eating. Probably not,
7 right?

8 DR. NICKOLS-RICHARDSON: This is
9 Shelly. I think we are the only other
10 subcommittee that looked at breakfast intake.

11 And for us, for Nutrient Adequacy, the Grade
12 is a II which we will present tomorrow.

13 DR. NELSON: I think we are okay
14 with this, unless, Joanne, if you feel
15 strongly. It's just they are inconsistent and
16 I think some of it has to do with the quality
17 of the breakfast more than anything.

18 DR. VAN HORN: Right. I was just
19 going to say, I think in what we'll hear
20 tomorrow there are more issues related to the
21 qualitative nature rather than the behavior of
22 eating breakfast.

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1 DR. NELSON: Exactly, that's what
2 I think. And as long as the implication is
3 such that, you know, high quality breakfast, I
4 think we are okay.

5 DR. PI-SUNYER: Okay, thank you
6 Mim and thank you Rafael. And let's go on to
7 Christine. She has a whole lot of questions.
8 We will let her go through them and then ask
9 questions. So Christine, you're on.

10 DR. WILLIAMS: I'd like to thank
11 Eve Essery and Jean Altman for all their
12 contributions to these questions. The
13 overarching question for this family of
14 questions is, how is dietary intake associated
15 with childhood adiposity? And of course, the
16 background for this question is the dramatic
17 increase in the prevalence of obesity among
18 U.S. children and adolescents over the past
19 several decades. Since the early 1970s
20 obesity has quadrupled among six to 11-year-
21 olds, tripled among 12 to 19-year-olds, and
22 more than doubled among preschool children.

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1 We know the dietary patterns among
2 U.S. children have changed significantly over
3 the past several decades concurrent with the
4 obesity epidemic. So the research questions
5 that we have chosen to address represent
6 dietary factors that have often been
7 hypothesized to promote or protect against
8 increased adiposity in children.

9 Since obesity results from a
10 positive energy balance it seems natural that
11 the first question relates to total energy:
12 Is intake of total energy (caloric) associated
13 with adiposity in children?

14 We conducted a full NEL review for
15 this question with a search for the NEL review
16 from 2004 to July 2009. And also distilled
17 the data from the previous ADA review, again,
18 children 0 to 18. We included cross-sectional
19 studies and studies from underdeveloped
20 countries. And we only included studies that
21 included some measure of adiposity as an
22 outcome variable.

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1 This review led to the proposed
2 conclusion that the preponderance of evidence
3 from a review of the recent scientific
4 literature tends to support a positive
5 association between total energy intake and
6 adiposity in children with a Grade III
7 (limited).

8 This conclusion was based on a
9 review of four studies published between 2004
10 and 2009. All four of them were longitudinal
11 cohort studies, and three of the four
12 longitudinal studies found a positive
13 association between total energy intake and
14 adiposity, and one found no association.
15 However, this study did not adequately assess
16 or adjust for implausible reports of energy
17 intake.

18 And these are the four studies
19 that were included in this review. All four
20 of the studies were conducted in the United
21 States, and all four earned a positive quality
22 ratings. And again three of the four found a

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1 positive association between total energy
2 intake and adiposity in children. Two of the
3 studies that saw the positive association, all
4 distinguish between plausible and implausible
5 reports of energy intake on an individual
6 basis, and the final study, Stunkard study,
7 measured total energy expenditure directly by
8 doubly labeled water.

9 The fourth study by Fulton did not
10 find a positive association. However, this
11 study didn't assess the plausibility of energy
12 intake, and also used less frequent measures
13 of dietary intake and measure by food
14 frequency questionnaire, whereas the others
15 were by food records with more frequent
16 measurements.

17 Some of the earlier ADA evidence
18 review were energy intake and overweight in
19 children included 45 studies, however, two-
20 thirds of them were cross-sectional studies,
21 and of the 15 longitudinal studies four found
22 a positive association between total energy

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1 intake and adiposity and ten did not, one
2 found a negative association.

3 These studies were all published
4 prior to 2004, and did not assess or adjust
5 the plausible reports of energy intake on an
6 individual basis.

7 So the ADA review concluded that
8 total energy intake measured using current
9 dietary assessment tools at that time which
10 may not accurately assess total energy intake
11 does not appear to have a strong association
12 with overweight in children. And again two-
13 thirds of those studies were cross-sectional
14 in nature.

15 And if you look at the data
16 related to plausible reports of energy intake
17 in studies in children you can see that, for
18 example, Huang was actually the first one to
19 look at this in any detail in a nationally
20 representative cross-section study of U.S.
21 children. And 55 percent of the children had
22 implausible energy intake. Then several other

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1 investigators have looked at this, again all
2 since 2004. And the percentage of children
3 with implausible energy intake varies from
4 about 36 to 38 percent, except for the Johnson
5 studies which were a little bit lower in
6 younger children.

7 So a significant number of
8 children with implausible energy intake. Next
9 slide. So before 2004 there was little
10 evidence that obese children consume more
11 energy than normal weight children. However,
12 studies since then have demonstrated that
13 unless the plausibility of energy intake is
14 assessed and accounted for in data analysis,
15 the link between energy intake and adiposity
16 is often masked.

17 Results from these
18 methodologically stronger studies contribute
19 to a growing body of evidence that, one,
20 overweight children, especially adolescents,
21 underreport energy intake to a much greater
22 extent than youth of normal weight; and two,

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1 that total energy intake among obese children
2 is greater than among normal weight children.

3 The NEL conclusion statement was
4 based on a small number of studies. However,
5 several were methodologically very strong, and
6 assessed and adjusted for implausible energy
7 intake reports. Overall, they provided
8 evidence that there is a positive association
9 between total energy intake and greater
10 adiposity in children. In view of the small
11 number of studies, however, the evidence was
12 assigned a Grade III or limited.

13 The evidence suggests that
14 strategies to prevent childhood obesity should
15 include efforts to reduce surplus energy
16 intake, especially energy from foods and
17 beverages that provide empty calories from
18 added sugars and solid fats.

19 The second sub-question that we
20 addressed had to do with dietary fat. Is
21 intake of dietary fat associated with
22 adiposity in children? And again this was

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1 based on a review, an NEL review that covered
2 January 2004 to 2009, and an ADA review, from
3 1982 to September 2004, with the same
4 inclusion/exclusion criteria.

5 And a review of the evidence led
6 to the proposed conclusion that a review of
7 the evidence suggests that increased intake of
8 dietary fat is associated with greater
9 adiposity in children, with a Grade II.

10 A review of the NEL evidence,
11 overall, there were six included studies.
12 Five were longitudinal and one was a clinical
13 trial. Of the five longitudinal studies there
14 were reports on three cohorts. Two of the
15 reports involved the STRIP cohort studied at
16 different ages, and two reports involved the
17 DONALD cohort study at different ages.

18 Three of the reports found a
19 positive association between total fat intake,
20 or intake of high fat foods and adiposity, in
21 all or a subsample of the population studied.

22 And two reports found no association.

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1 The one randomized clinical trial
2 found no association between total fat intake
3 and adiposity in children.

4 And these are more details from
5 the six included studies in the NEL review.
6 One is a randomized controlled trial; and five
7 longitudinal. For the STRIP study you can
8 see the Hakanen study in the middle, a 2006
9 study of children at 10 years of age, and they
10 found that after two years of age there were
11 continuously fewer overweight girls in the low
12 fat, low saturated fat, low cholesterol diet
13 intervention group than in the control group.

14 And then, Niinikoski in the bottom
15 also studied children at 14 years of age, and
16 found that at that time there was no
17 difference between the intervention and the
18 control group in both BMI or pubertal
19 development. And the other studies, you can
20 see that the three with positive outcomes, and
21 three with no association.

22 When you look at the ADA evidence,

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1 there were 21 longitudinal studies in the ADA
2 evidence review, and 12 of those studies found
3 a positive association between total fat
4 intake or intake of high fat foods and
5 adiposity, in all or a subsample of the
6 population, and nine found no association.

7 And their conclusion was that
8 dietary fat intake is associated with higher
9 adiposity in children with a Grade II. Their
10 review also included 34 cross-sectional
11 studies. However we did not consider these in
12 the NEL combined review process.

13 And this is a very busy slide, but
14 just to give you a flavor for the 21
15 longitudinal studies in the ADA review, and
16 the top ones in green were the ones that found
17 a positive association for the most part
18 between dietary fat and adiposity. The lower
19 -- the ones at the bottom found no
20 association. And one of the things that
21 differentiated the positive studies was that
22 more of them had multiple measures of

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1 adiposity, and not just BMI. Which I think
2 is important because BMI has been found to be
3 a relatively poor surrogate measure of
4 adiposity in children as based on the Friedman
5 report of 2009.

6 So when you combine the evidence
7 from the NEL and the ADA evidence review, you
8 are left with 27 methodologically stronger
9 studies that were RCTs or longitudinal
10 studies, and 15 of the 27 studies, all
11 longitudinal, found a positive association
12 between total fat intake or intake of high fat
13 foods and adiposity in all or a subsample of
14 the population studied. And 12 found no
15 association.

16 Again the proposed conclusion was
17 that the review of the evidence suggests that
18 increased intake of dietary fat is associated
19 with greater adiposity in children, with a
20 Grade II. Next slide.

21 The implications, diets high in
22 total fat can theoretically result in passive

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1 over-consumption of energy, since fat is so
2 palatable and energy-dense, yielding more than
3 twice the calories per gram as carbohydrate or
4 protein. Although the percent of energy from
5 total fat has decreased over the past several
6 decades, currently one-fourth of U.S. children
7 still have average daily intakes that exceed
8 the IOM acceptable macronutrient range for
9 age.

10 After consumption of MyPyramid
11 core foods for nutrient requirements at
12 recommended energy levels, there are few
13 discretionary calories remaining, only about 8
14 to 20 percent before energy needs are
15 exceeded. Unfortunately about 40 percent of
16 the total energy intake for 2- to 18-year-old
17 children comes from empty calories, of which
18 about half comes from solid fats, which
19 contribute to energy surpluses as well as
20 elevated blood cholesterol.

21 Evidence from both NEL and the ADA
22 reviews support a positive association between

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1 total fat intake and increased adiposity in
2 children, thus total fat should not exceed the
3 IOM acceptable ranges and should consist
4 primarily of mono- and polyunsaturated fats
5 that promote heart health and provide
6 essential fatty acids for growth and
7 development.

8 The third sub-question that we
9 will review at this time has to do with
10 calorically-sweetened beverages, and the
11 question is, is intake of calorically-
12 sweetened beverages associated with adiposity
13 in children? And again, this evidence was
14 based on the NEL review from 2004 to 2009, and
15 on a previous ADA review from 1982 to 2004,
16 with similar exclusion/inclusion criteria.

17 The proposed conclusion: a
18 moderate amount of evidence supports the
19 conclusion that greater intake of calorically-
20 sweetened beverages is associated with
21 increased adiposity in children, with a Grade
22 II.

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1 And the NEL review was based on 11
2 included studies, 10 are longitudinal and one
3 was an RCT. Of the 10 longitudinal studies,
4 seven found a positive association between
5 intake of calorically-sweetened beverages and
6 adiposity in all or a subsample of the
7 population studied. Three found no
8 association. And the one randomized
9 controlled trial by Ebbeling found some
10 evidence for a positive association between
11 intake of calorically-sweetened beverages and
12 adiposity.

13 These are the 11 primary studies
14 and the one trial in the NEL review. You can
15 see the top seven that have a positive
16 association with adiposity in children; and
17 the bottom three that had no association.

18 In review of the ADA evidence
19 which goes back to 1982, there were six
20 longitudinal studies in this review, three of
21 the six found a positive association between
22 intake of calorically-sweetened beverages and

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1 adiposity, and three studies found no
2 association. One RCT found evidence of a
3 positive association. And their conclusion
4 statement was that intake of calorically-
5 sweetened beverages is positively associated
6 with adiposity in children with a Grade II.

7 The ADA Evidence Review also
8 included 13 cross-sectional studies. However,
9 again, these were not considered in the NEL
10 combined review process. Next slide.

11 And for the combined review of the
12 NEL and the ADA evidence, there were 18
13 included studies, randomized controlled trials
14 and longitudinal studies. And, overall, of
15 those 18 studies 12 of them found a positive
16 association between calorically-sweetened
17 beverage intake and adiposity in all or a
18 subsample of the population studied, and six
19 found no association.

20 Of the randomized controlled
21 trials there were two, in the combined review,
22 one by Ebbeling which was among 13 to 18-year-

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1 old children, and in this study, only for the
2 heaviest children in the top tertile the
3 increase in BMI was less than in the
4 intervention group compared to the controls,
5 and this was with home delivery of non-caloric
6 beverages to displace sugar-sweetened
7 beverages. And in the James study a one-year-
8 based nutritional education program in schools
9 focused on decreasing intake of carbonated
10 beverages.

11 The percent of overweight and
12 obese children increased in the control group,
13 but decreased slightly in the intervention
14 group. So there was a significant difference
15 between the treatment groups. Next slide.

16 For implications: the principal
17 sources of energy among children are intended
18 to be the MyPyramid core foods - grains,
19 meats, fruits, vegetables and dairy - in order
20 to meet recommended intakes of essential
21 nutrients within estimated energy
22 requirements.

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1 And again after consumption of
2 core foods for nutrient requirements, there
3 are few discretionary calories remaining, only
4 about 8 to 20 percent, before energy needs are
5 exceeded. Unfortunately about 40 percent of
6 children's total energy intake comes from less
7 nutritious sources of energy - added sugars
8 and solid fats - contributing to energy
9 surplus and risk of obesity. Calorically-
10 sweetened beverages are a major source of
11 added sugar among children; most providing
12 energy without other nutrients.

13 Evidence from both the NEL and the
14 ADA reviews, especially data from the larger,
15 methodologically stronger and higher quality
16 studies, supports a positive association
17 between calorically-sweetened beverage intake
18 and increased adiposity in children.

19 Thus consumption of calorically-
20 sweetened beverages in children should be
21 discouraged. One, because of the positive
22 association with increased adiposity, and two,

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1 because of the need to replace empty calories
2 with nutrient-rich energy sources for optimal
3 growth and development.

4 So again the proposed conclusion
5 is that there is a positive association
6 between intake of calorically-sweetened
7 beverages and adiposity in children with a
8 Grade II.

9 The next question we reviewed has
10 to do with calcium and dairy, milk and milk
11 products. Is intake of calcium and/or dairy
12 (milk and milk products) associated with
13 adiposity in children?

14 And, again, this is based on a
15 combined review of the NEL review from 2004 to
16 2009, and the ADA review which goes back to
17 1982. Next slide.

18 And the proposed conclusion: the
19 NEL review provides little convincing evidence
20 that intake of calcium and/or dairy - milk and
21 milk products - plays a significant role in
22 regulating adiposity in children and

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1 adolescents, with a Grade III.

2 And the NEL review identified 13
3 articles that were included in this review,
4 five were longitudinal studies, and five were
5 randomized controlled trials, and three were
6 systematic reviews. Next slide.

7 The randomized controlled trial,
8 one randomized controlled trial found evidence
9 for a negative protective association between
10 intake of calcium or dairy and adiposity for
11 the children studied. And two trials found no
12 association between intake of calcium/dairy
13 and adiposity.

14 And two trials found mixed
15 results.

16 Of the trials that found mixed
17 results, one found that higher habitual
18 dietary calcium intake was inversely
19 associated or protective body fat, however,
20 calcium supplement had no effect on weight,
21 height or body fat in girls.

22 And the other study by DeJongh

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1 found no differences in fat mass between
2 calcium supplemented and placebo groups, and
3 no association between percent body fat and
4 fat mass changes and dietary calcium intake or
5 total calcium. However, for children with the
6 lowest dietary calcium intakes, that net gain
7 was lower in the calcium-supplemented versus
8 placebo group. Next slide.

9 For the longitudinal study there
10 were five in the NEL review, and two of the
11 five longitudinal studies found evidence for a
12 negative or protective association between
13 intake of calcium and dairy and adiposity in
14 children. One found no association and one
15 large longitudinal study of adolescents
16 reported a positive association - increased
17 weight gain - between intake of calcium/dairy
18 and adiposity.

19 And the final study found mixed
20 findings, in the study, with
21 hypercholesterolemic or non-
22 hypercholesterolemic children. Next slide.

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1 We also considered the evidence
2 from -- actually that should be three - three
3 systematic reviews, one by Barr, one by Lanou
4 and one by Winzenberg. And, overall, they all
5 three concluded that there was insufficient
6 evidence that calcium or dairy was protective
7 against adiposity in children. I won't go
8 through all the details. Next slide.

9 This summarizes the ten primary
10 studies in the NEL review for calcium, dairy
11 and adiposity in children. The five RCTs at
12 the top and the five longitudinal studies on
13 the bottom. And you can see that the results
14 were quite mixed between positive, no
15 association and negative. Mostly no
16 association for - or weakly protective. Next
17 slide. In reviewing the earlier ADA evidence
18 that goes back to 1982, they reviewed them
19 separately, although many of the same articles
20 were included in both reviews. There were
21 four longitudinal studies that looked at
22 calcium and adiposity in children, and there

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1 were three cross-sectional studies. Two of
2 the four longitudinal studies found a positive
3 association, and two found a positive and one
4 found a negative association, and they
5 concluded that a low intake of calcium may be
6 associated with increased adiposity.

7 Both for dairy and adiposity in
8 children there were 15 studies, ten of these
9 were cross-sectional however, and only four
10 were longitudinal studies -- five were
11 longitudinal, sorry -- and of the five
12 longitudinal studies four of them found no
13 association between intake of dairy and
14 adiposity and one found a negative protective
15 association.

16 Again they concluded that research
17 indicates that a low intake of dairy may be
18 associated with increased adiposity among
19 children. However, their conclusions were
20 based on a significant number of cross-
21 sectional studies.

22 If you combine the NEL and ADA

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1 reviews, and only look at the randomized
2 controlled trials and the longitudinal
3 studies, there were five randomized controlled
4 trials in the combined review, and again,
5 primarily no association or mixed association,
6 with one, primarily the bottom one, protective
7 against adiposity in children. Next slide.

8 The 12 longitudinal studies, five
9 from the NEL review, and seven from the ADA
10 review. There were primarily either no
11 association or for a few studies, a negative
12 protective association or mixed. Next slide.

13 So for the combined reviews of NEL
14 and ADA, the 12 longitudinal studies, six
15 found no association between calcium and/or
16 dairy and adiposity, four found a negative
17 protective association, one found mixed
18 results, and one found a positive association
19 between weight gain over four years.

20 Thus when you look at the combined
21 evidence, there are 17 studies of either
22 controlled trials or longitudinal studies, and

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1 of these 17 studies 8 found no association,
2 five found inverse protective effect, three
3 found mixed results, and one found a positive
4 association.

5 Thus we felt that the
6 preponderance of evidence of these studies was
7 greatest for no association, although there
8 was some evidence for a weak protective
9 association.

10 The NEL review also included the
11 three systematic review articles, and these
12 reviews concluded that the preponderance of
13 evidence did not support a protective
14 association between intake of dairy/calcium
15 and adiposity.

16 Next slide. So although the NEL
17 review provides insufficient evidence that
18 intake of calcium and/or dairy, milk and milk
19 products, plays a significant role in
20 regulating adiposity in children and
21 adolescents, milk and milk products have
22 traditionally been a source of nutrient-rich

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1 foods and beverages for children and
2 adolescents. Besides providing energy, they
3 are a concentrated source of highly
4 bioavailable calcium, providing about three-
5 fourths of the calcium in the U.S. diet.

6 In addition, they are a rich
7 source of essential amino acids, have a good
8 balance of macronutrients, and are rich
9 sources of riboflavin and contain high quality
10 protein. Although some studies suggest a
11 protective effect of dairy intake against
12 obesity in adults and children, others have
13 found no association or in some cases even a
14 positive association with adiposity.

15 But, regardless of evidence for or
16 against the role of regulating adiposity,
17 children should be encouraged to consume
18 recommended servings of low fat dairy products
19 daily in order to meet recommended dietary
20 intake levels for key nutrients such as
21 calcium. Next slide.

22 The final sub-question that we

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1 will review today is, is intake of dietary
2 fiber associated with adiposity in children?
3 And again this is not a question that was
4 reviewed by ADA, so this was only an NEL
5 review that extended back to 1980 through July
6 of 2009.

7 And the proposed conclusion: since
8 so few clinical trials and longitudinal cohort
9 studies have examined the association between
10 dietary fiber intake and changes in adiposity
11 in children, there is insufficient evidence at
12 the present time to support the hypothesis
13 that dietary fiber may protect against
14 increased adiposity with a Grade III
15 (limited).

16 The NEL review identifies five
17 included studies. Two of them were trials and
18 three were longitudinal studies. Of the two
19 randomized controlled trials, Ventura found an
20 inverse, protective effect of dietary fiber on
21 adiposity in the 16-week trial of 54
22 overweight Latino adolescents aged 15. The

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1 increased dietary fiber intake had an
2 improvement in BMI which decreased, and
3 visceral adipose tissue, minus 10 percent
4 versus no change in the control group.

5 And the other study by Vido found
6 no benefit of a dietary fiber supplement on
7 weight change in 60 overweight Italian
8 children. At the end of the intervention
9 weight decreased in both treatment groups, no
10 significant difference between the groups.

11 And for the last three
12 longitudinal studies, Berkey et al. studied
13 dietary intake and physical activity among a
14 large number of U.S. children 9 through 14,
15 and found no significant associations between
16 energy-adjusted dietary fiber or dietary fat
17 and BMI.

18 And Cheng assessed dietary intake
19 and adiposity in a cohort of 215 German
20 adolescents. And, again, they found that
21 neither dietary fiber intake, whole grain
22 intake, dietary glycemic intake nor glycemic

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1 load were associated with changes in percent
2 body fat or BMI Z-score throughout puberty.

3 Newby measured dietary intake and
4 adiposity at baseline and again six to 12
5 months later in a cohort of low-income U.S.
6 preschool children enrolled in the WIC
7 program. In this population, intake of total
8 dietary fiber was not associated with weight
9 change, however, intake of WIC-defined breads
10 and grains was associated with a lower weight
11 change per year. Next slide.

12 And this is a summary of the five
13 studies included in this review. Again, four
14 of them showing no association, and the one
15 trial, by Ventura, showing negative protective
16 effect.

17 Dietary fiber is often a marker
18 for a healthy, nutrient-rich diet in
19 childhood, it's associated with greater
20 intakes of Vitamin A, B-6, B-12, C, and
21 niacin, thiamin, riboflavin, folate,
22 magnesium, iron, zinc and calcium, and an

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1 increased number of servings of Food Guide
2 Pyramid food groups. Children with higher
3 fiber intake have also been shown to have
4 lower total fat, saturated fat, mono-
5 unsaturated fat, and sucrose intake and higher
6 protein intake compared with children with
7 lower fiber intake.

8 Higher dietary fiber is also
9 associated with lower serum cholesterol
10 concentrations in children and adolescents, in
11 a recent paper from the STRIP study. And
12 dietary fiber also plays an important role in
13 supporting healthy gastrointestinal function
14 and normal laxation in children.

15 The role of dietary fiber in
16 weight management in children and adolescents
17 however is less clear. Theoretically, high
18 fiber diets could promote a healthy weight
19 since high fiber foods require more time to
20 chew, slowing down the rate at which food is
21 eaten and allowing more time for satiety
22 signals; fiber absorbs fluid, increasing the

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1 bulk of ingested food and promoting a feeling
2 of fullness. High fiber foods are generally
3 lower in energy density, having fewer calories
4 than the same weight of low fiber foods.

5 Unfortunately, very few studies
6 have examined the association between dietary
7 fiber intake and adiposity in children. Thus,
8 at the present time, there is insufficient
9 evidence for a protective role.

10 Higher dietary fiber intake
11 however, as part of a healthy dietary pattern
12 that also includes lower intake of dietary fat
13 and reduced energy density has been shown to
14 be associated with decreased adiposity in
15 young children.

16 At present, the majority of U.S.
17 children consume far less than the recommended
18 14 grams of dietary fiber per 1000 calories.
19 Thus, regardless of evidence for or against
20 the role in regulating adiposity, children
21 should be encouraged to consume greater
22 amounts and varieties of high fiber foods in

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1 order to increase nutrient density and promote
2 healthy lipid profiles, glucose tolerance, and
3 normal gastrointestinal function.

4 DR. PI-SUNYER: Okay, thank you
5 very much, Christine, for this incredible
6 piece of work. These are now open for
7 discussion. Any comments for Christine?

8 DR. PEREZ-ESCAMILLA: Christine,
9 this is Rafael, and I have first of all to
10 congratulate you for a most comprehensive
11 presentation. My question is related to the
12 grade level that you gave to the calcium and
13 dairy question in relationship to childhood
14 adiposity, because you gave it a Grade III,
15 and it seems to me that you have a very
16 substantial number of well designed studies,
17 randomized controlled trials, longitudinal
18 studies, systematic reviews and so on, that
19 would lead me to believe that the grade should
20 be stronger than that. I'm not sure that
21 doing 20 more studies in that area is going to
22 change the distribution of results that you

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1 have. If I do a mental meta-analysis of what
2 you just presented it seems there is no
3 relationship between calcium/dairy and
4 childhood adiposity.

5 DR. WILLIAMS: That is a good
6 question, Rafael. I think we found it a Grade
7 III mostly because the evidence is so mixed,
8 but you're right that there are a significant
9 number of included studies, so I'm willing to
10 revisit that.

11 DR. PI-SUNYER: It seems to me
12 that you do have enough evidence that you have
13 shown us for a II rather than a III.

14 DR. NELSON: This is Mim. I
15 would agree with that.

16 DR. CLEMENS: Christine, this is
17 Rog. Really nice work, thank you so much.
18 Question: did your team examine various dairy
19 components that may impact satiety signaling
20 therefore have an impact on food intake?

21 DR. WILLIAMS: No, we didn't.

22 DR. CLEMENS: I think to Rafael's

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1 point there might be - you might get a
2 stronger signal, no pun intended, as you look
3 at various dairy components. It may well be
4 the composition of those dairy components that
5 would have an overall effect versus the entire
6 category.

7 DR. WILLIAMS: There could be. I
8 don't think there was enough information in
9 the studies that we reviewed to look at that.

10

11 DR. APPEL: This is Larry. I
12 have two questions, or actually one suggestion
13 and one question. The total energy section,
14 you don't mention in your implications or in
15 the conclusion that these studies, unless I'm
16 really off-base, did not measure physical
17 activity particularly well. So in that
18 setting I think it's really quite hard to
19 discuss total energy as opposed to energy
20 balance or deficit or difference. And I was
21 just suggesting that you add something about
22 the inadequate measurement of physical

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1 activity being a major hindrance to
2 understanding intake.

3 DR. WILLIAMS: That's a good
4 point, Larry. It was measured better in some
5 studies than others, and I didn't include it
6 in this writeup but some of them did measure
7 it with accelerometers or questionnaires, but
8 some did better than others.

9 DR. APPEL: But even with
10 accelerometers, it's pretty weak, and most
11 questionnaires don't do a good job, so I think
12 it really needs to be a strong caveat in the
13 implications.

14 DR. WILLIAMS: Okay. Thank you.

15 DR. APPEL: The other, it's a
16 question, and I don't know if there is a
17 subtle distinction here. But in the sweetened
18 beverages, you put "calorically-sweetened
19 beverages" as opposed to "sugar-sweetened
20 beverage". That's what we talked about in
21 adults; this is what is the term [inaudible]
22 switched. And I don't know if there was some

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1 reason for that, or if it's accidental.

2 DR. WILLIAMS: I think that was
3 the way it was phrased in the original ADA
4 review, but I think a lot of people use the
5 terms interchangeably, so we should probably
6 be consistent and use it one way or the other.

7 DR. NELSON: I think we are
8 mostly using "sugar-sweetened beverages".

9 DR. WILLIAMS: So we could change
10 that.

11 DR. NELSON: This is Mim, I have
12 two questions. One, is the lack of strength
13 with dietary fiber, is that because just
14 everybody is so low that nobody is sort of
15 meeting a threshold that would make a
16 difference?

17 DR. WILLIAMS: Well, that's
18 possible. I think there were just so few
19 studies.

20 DR. NELSON: Okay, because it
21 seems like one of the issues just might be
22 literally, children the intake is so low, that

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1 was just a comment. And then back to the
2 sugar-sweetened beverages, it seems like when
3 you add - I might argue for even a Grade I -
4 there is a lot - between all the years of
5 study of this, it seems like it may be
6 stronger than a Grade II. I just might argue
7 for - I know that like every single study
8 doesn't show it but there is a lot of evidence
9 there both in RCTs and prospective trials. I
10 wonder what the rest of the Committee thinks.

11 DR. PI-SUNYER: Well, there
12 aren't many RCTs.

13 DR. NELSON: Two, but yes but a
14 few decades.

15 DR. PI-SUNYER: And they are not
16 very good, most of them are carried out over a
17 very long period of time.

18 DR. WILLIAMS: It was kind of
19 limited, even in those trials. It could
20 possibly be a I to II, but I kind of lean
21 toward the II.

22 DR. VAN HORN: One of the rate-

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1 limiting steps in all of the literature
2 related to children appears to be the
3 variability in the diet assessment
4 methodology. For example there are studies
5 especially related to dietary fiber where, for
6 example, in the one study that discusses a
7 fiber supplement, there is no assessment of
8 the rest of the fiber in the diet. So
9 obviously one has ask yourself, what does that
10 really mean? So I think unfortunately,
11 especially earlier on, many of these studies
12 which involve food frequency questionnaires or
13 other less precise methods leave you wondering
14 about, not only the fact that just as in
15 adults overweight children underreport their
16 intake et cetera, but the methods used to
17 assess it are even more difficult in children
18 than they are in adults, so I think we suffer
19 a little bit from that.

20 But one of the aspects that I find
21 especially intriguing is - and perhaps we will
22 address some of this tomorrow when we discuss

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1 the modeling issues. But when you look at the
2 NHANES data and you begin to put patterns
3 together, and Chris mentioned this in her
4 magnificent overview of all these factors,
5 which is just unbelievable, that there is an
6 interesting finding in that those children who
7 consume dietary fiber, increased dietary fiber
8 is associated with lower total fat, lower
9 saturated fat, lower sugar, added sugars,
10 lower sugar-sweetened beverages. In other
11 words, I believe as we go forward and take the
12 best of what the evidence provides, we can
13 also look at the actual eating behavior of
14 American children today and get some ideas
15 about patterns that lend themselves to more
16 nutritious as well as less obesity-associated
17 types of eating patterns. I think once our
18 research data run out then we are left to look
19 at exactly what kind of eating patterns might
20 protect and promote a healthier outcome.
21 Would you agree with that, Chris?

22 DR. WILLIAMS: That's a good

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1 point. I think also, when you look at a lot
2 of the studies, they use multiple measures of
3 diet assessment, multiple measures of
4 adiposity, and stratify by different
5 variables, and often measure intake both in
6 absolute terms, gram intake, or percent of
7 energy, so there were so many different
8 variables in the study to kind of sort
9 through. But in the end I think the body of
10 evidence was strong for many of the questions.

11 DR. APPEL: This is Larry again.

12 You know, in this section, I think there is
13 an important piece of the puzzle that should
14 come out in the implications but doesn't, and
15 it's the amount of calories and the percent of
16 calories from explicitly sugar-sweetened
17 beverages. And where you have it now, it's
18 sort of buried as a percent of calories from
19 added sugars and solid fats, which doesn't hit
20 the point head on from what - at least in 2005
21 when we looked at calorie sources, it was like
22 20 percent of calories came from sugar-

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1 sweetened beverages in certain subgroups of
2 children, and I think that really needs to
3 come out as part of the puzzle; it's not
4 directly cohort studies, but I think that is
5 contextual material that is incredibly
6 important.

7 DR. WILLIAMS: I agree.

8 DR. VAN HORN: And along that
9 line the fact that up to 40 percent of
10 calories are coming from what one would
11 consider snacks and desserts and foods of that
12 nature is really quite disturbing. The idea
13 of again focusing attention on the need to
14 consume proper food, as snacks and as desserts
15 et cetera, really has to come out loud and
16 clear.

17 DR. RIMM: This is Eric. Can I
18 raise my point for the third time. I guess we
19 should talk about it once again, the issue of
20 the dietary fat proposed conclusion. I guess
21 my reading, and I think the way Christine has
22 put together the implications which are very

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1 nice, which essentially says that children
2 should not be eating above the IOM report
3 recommendations for fat for children, which
4 is, if I can recall, is 25 - 35 percent of
5 calories from fat. I think that is consistent
6 with what we are saying for adults in terms of
7 fat composition, but the way I read this
8 conclusion is that, all kids should be on a
9 low fat diet. I am concerned that a low fat
10 diet will increase the sugar-sweetened
11 beverages and the refined grains. So I don't
12 know - I know that we talked about this before
13 in our previous subcommittee call, and I think
14 Joanne and Larry and a few others agreed that,
15 I think the evidence doesn't necessarily point
16 to the fact that a lower fat diet is
17 beneficial, and in a few of the studies where
18 it was lower saturated fat it was beneficial,
19 but that the evidence doesn't support
20 necessarily that there is a difference in what
21 we should give for guidelines between children
22 and adults.

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1 DR. PI-SUNYER: Well, how would
2 you like to fix that, Eric, by putting an
3 actual range in here?

4 DR. RIMM: The implications do
5 say that, and I think several of the cohort
6 studies that you cite where there is an
7 association between fat and weight gain, it is
8 at levels above 35 percent of calories from
9 fat, but I think if we are going to say
10 something here, and say that the evidence is
11 Grade II, which to me is pretty strong given
12 what's here, is that we maybe should try to
13 quantitate it so that people see that it is
14 not different than what we are saying for
15 adults.

16 DR. PI-SUNYER: I think that is a
17 good idea. I think that would clarify things.

18 DR. WILLIAMS: I think we did put
19 that in the implications though, that children
20 should stay within the recommended range.

21 DR. RIMM: But right now the
22 conclusion, if I was a food service provider

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1 looking at the conclusion in dietary fat, it
2 would say, eat low fat foods. Or if I was a
3 parent or if I was someone trying to interpret
4 this, it does suggest eating low fat foods.
5 And I am concerned that that is what we said
6 in the '70s to adults, and everybody went to
7 low fat foods and ate nonfat yogurt, and I
8 think that contributed to some of our weight
9 gain issues, because we didn't follow the rest
10 of the guidelines, and get our fruits and
11 vegetables, but instead ate processed
12 carbohydrates. And that's what all of us are
13 concerned about and have been talking about
14 with the fiber guideline.

15 DR. WILLIAMS: I think the key
16 thing is to be careful about not overconsuming
17 fat in the diet because it is so energy dense.

18 DR. RIMM: But our energy
19 conclusion is only Grade III. So I understand
20 the reason why we don't want to eat energy
21 dense foods. It's just that in all the trials
22 for humans where you look at a high fat versus

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1 low fat diet it doesn't work. So there is no
2 evidence here to me that says, trials among
3 kids, where you are focusing just on total
4 fat, that it did work. All we have is a
5 trial, the STRIP study, which is a low
6 saturated fat, high exercise, make sure your
7 parents don't smoke, trial. And at age nine
8 it only worked in the girls, and in age 14
9 there is no weight difference. So I'm not
10 convinced that the evidence should really be
11 different between kids and adults, and I am
12 worried that we are going to give the wrong -
13 I think we should have kids not eating at fast
14 food restaurants, rather than trying to guide
15 them into low fat foods.

16 DR. NELSON: This is Mim. I
17 completely agree. But, so, it's more the way
18 this is presented in the conclusion, isn't it,
19 that it should be a range as opposed to lower
20 intake of dietary - like lower intake of
21 dietary fat.

22 DR. PI-SUNYER: I think Chris can

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1 fix this very easily by just putting in that
2 IOM range.

3 DR. WILLIAMS: That is no
4 problem. I think that is a good suggestion.

5 DR. VAN HORN: I think that the
6 point really is also that no one is suggesting
7 a low fat diet of 30 percent of calories is
8 not low fat. So I think the data that
9 document a higher fat, and especially a higher
10 saturated fat intake, it really does come out
11 loud and clear. So an emphasis on reducing
12 saturated fat seems totally appropriate, and
13 again, perhaps emphasis on the foods that
14 should be eaten, i.e., the complex
15 carbohydrates, higher fiber foods appear to
16 help achieve the recommended nutrient
17 composition that is really being advertised --

18 DR. RIMM: I wonder if that could
19 be one of the implications, what you just
20 said, Linda, specifically focusing on
21 saturated fat, because right now I think it's
22 just on total fat, and I think there are

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1 benefits to kids from the healthy fats. And
2 so again I don't see any demarcation that
3 says, adolescents are different than adults in
4 terms of what we should be advising here. And
5 I think we should have something in the
6 implications that maybe specifically focuses
7 on saturated fat so we are in line with fast
8 food restaurants and all the other guidance we
9 are giving.

10 DR. NELSON: And that would be
11 complementary to the rest of the report, too.

12 DR. RIMM: Right, it's
13 consistent.

14 DR. PI-SUNYER: Yes, I think we
15 could include that.

16 DR. RIMM: The last implication
17 is about the benefits of monos and polys, but
18 maybe we should put upfront about the
19 detrimental effects of saturated fats.

20 DR. PI-SUNYER: Okay, thank you,
21 Eric. Thank you very much, Chris.

22 I think we need to move on,

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1 because we don't have much time. The next
2 session is on macronutrient proportion and
3 body weight. And Joanne and I worked on this
4 particularly but all of the subcommittee
5 somewhat. So the overall question is what is
6 the relationship between macronutrient
7 proportion and body weight and other questions
8 are, what is the optimal macronutrient
9 proportion to maintain a health weight? To
10 lose weight if overweight or obese? And for
11 weight loss maintenance? And then, are low
12 carbohydrate hypocaloric diets safe and
13 effective for long term weight loss and
14 maintenance, and are high protein hypocaloric
15 diets safe and effective for long term weight
16 loss and maintenance? Next slide please.

17 The search strategy you see here,
18 we went back to June of 2004, included
19 adults 19 and older and had the outcome
20 measures you see there, overweight, obesity,
21 BMI, percent fat, waist-to-hip ratio, weight
22 gain and weight loss.

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1 The overall research question:
2 what is the relationship between macronutrient
3 proportion and body weight? Next slide.

4 Proposed conclusion: when calorie
5 intake is controlled the macronutrient
6 proportion of the diet is not related to
7 maintaining a healthy body weight, losing
8 weight or avoiding weight gain. Weight loss
9 can be achieved through changing macronutrient
10 proportions. But this effect does not last.
11 Dietary patterns with macronutrient
12 proportions that are outside the Dietary
13 Reference Intakes are difficult to maintain
14 over the long term and also raise some safety
15 questions.

16 Next question: what is the optimal
17 proportion of dietary fat, carbohydrate and
18 protein to maintain a healthy body weight?
19 The conclusion, the limited number of studies
20 that address this suggest that carbohydrate
21 intake is negatively associated with BMI, and
22 that normal body weight is associated with a

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1 carbohydrate intake at the level of 40 to 65
2 percent of total calories. Next slide.

3 The two studies that lead to this
4 conclusion particularly are these two, and
5 unfortunately, they are both cross-sectional
6 studies. Both studies found that normal
7 weight subjects were more likely to consume a
8 diet higher in carbohydrates than overweight
9 or obese individuals. Next slide.

10 What is the optimal proportion of
11 dietary fat, carbohydrate and protein to lose
12 weight if one is overweight or obese? And the
13 conclusion: when overweight/obese persons
14 attempt to lose weight with reduced calorie
15 intake, there are no differences in weight
16 loss with differing macronutrient proportions
17 if diets are followed for longer than six
18 months. In shorter-term studies low-calorie,
19 high-protein diets may result in greater
20 weight loss, but these differences are not
21 sustained over time.

22 With regard to loss of weight, you

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1 can see, we looked at 36 articles. Five
2 systematic reviews, 31 RCTs, and one non-RCT.

3 Twenty studies found no relationship between
4 macronutrient proportion and weight loss; 13
5 studies found that low carbohydrate diets are
6 more effective than low fat diets, or higher
7 carbohydrate diets. Four studies found that
8 high protein diets are more effective than
9 low or moderate protein diets.

10 These are the trials. I'm not
11 going to go through them. You can see most of
12 them are randomized controlled trials which is
13 pretty good. But you can see on the right
14 that most of them have a zero with a slash
15 through them showing no difference in effect.

16 What is the optimal proportion of
17 dietary fat, carbohydrate and protein to avoid
18 regain in weight reduced persons? There are
19 no data to suggest that any one macronutrient
20 proportion is more effective for avoiding
21 weight regain in weight reduced persons.

22 This, we looked at 12 articles.

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1 Two systematic reviews, nine RCTs and one
2 prospective cohort study. Ten studies found
3 no relationship between macronutrient
4 proportion and weight loss. One study found
5 that a low carbohydrate diet was more
6 effective than a low fat diet, and one study
7 found that a higher protein diet resulted in
8 better weight maintenance than a lower protein
9 diet.

10 And here you see again randomized
11 controlled trials showing little relationship
12 between - no relationship between
13 macronutrient proportion and weight loss
14 maintenance. Next slide.

15 Are low carbohydrate hypocaloric
16 diets safe and effective for long-term,
17 greater than six months, weight
18 loss/maintenance? Diets with less than 45% of
19 calories as carbohydrates are not more
20 successful for long-term weight loss, that is,
21 followed up to 12 months. There is also some
22 evidence that they may be less safe. Next

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1 slide.

2 And here we looked at 15 articles,
3 3 systematic reviews, 9 RCTs and 4 prospective
4 cohort studies. Nine of the studies found no
5 relationship between macronutrient proportion
6 and weight loss. Two studies found that low
7 carbohydrate diets are more effective than low
8 fat diets. And two studies found that low
9 carbohydrate diets were associated with
10 increased mortality, especially cardiovascular
11 disease mortality.

12 Here you can see the list of
13 studies, most of them RCTs showing no effect
14 with regard to differences. The last two
15 trials, the Lagiou trial and the Trichopoulou
16 trial, are two trials that were done in
17 Greece, and they followed patients for a
18 longer period of time, and reported that with
19 a lower carbohydrate, higher protein diet
20 there was a higher cardiovascular disease
21 mortality and increased total mortality.

22 It's on the basis of only these

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1 two trials that we put in the thing about
2 safety, that they might be less safe. Next
3 slide, please.

4 Are high protein hypocaloric diets
5 safe and effective for long term weight loss/
6 maintenance? Intake of diets higher in
7 protein than accepted standards, greater than
8 35 percent of total calories, provide no
9 advantages for weight loss or weight
10 maintenance or for improved health biomarkers
11 compared to other diets with differing
12 macronutrient composition. Also such diets
13 may be less safe than diets within the DRI
14 ranges for macronutrients.

15 And here you see there are less
16 studies available, three RCTs and one cohort
17 study. The three studies, the three RCTs,
18 found no relationship between macronutrient
19 proportion and weight loss, and one study
20 found that diets lower in carbohydrate and
21 higher in protein were associated with
22 increased mortality, especially cardiovascular

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1 disease mortality. And that Trichopoulou
2 study is the same one I quoted earlier for the
3 low carbohydrate, high protein diets.

4 What is the relationship between
5 macronutrient proportion and body weight? So,
6 the overall conclusion is that when calorie
7 intake is controlled the macronutrient
8 proportion of the diet is not related to
9 maintaining a healthy body weight, losing
10 weight or avoiding weight gain. Weight loss
11 can be achieved through changing macronutrient
12 proportions, but this effect does not last.
13 Dietary patterns with macronutrient
14 proportions that are outside the Dietary
15 Reference Intakes are difficult to maintain
16 over the long term, and also raise some safety
17 questions. Next slide, please.

18 I will go on and deal with this
19 and then ask for questions. This is the
20 effect of weight loss in older adults on
21 health outcomes. And the research question
22 is, for older adults, those aged 65 and over,

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1 what is the effect of weight loss versus
2 weight maintenance on selected health
3 outcomes, cardiovascular disease, type 2
4 diabetes, cancer, and mortality?

5 This question was not addressed in
6 the 2005 Dietary Guidelines Report. We
7 searched back further because it wasn't
8 addressed in 2005, so we went back to 1995,
9 included older adults above age 65, and looked
10 at cardiovascular disease, type 2 diabetes,
11 cancer and mortality. The proposed
12 conclusion, which is a Grade II, in older
13 adults mortality associated with BMI is U-
14 shaped, increasing below 18.5 and also rising
15 beginning at BMI 27 to 34, depending on the
16 study. Weight loss in older adults is
17 associated with increased risk of mortality.
18 Most studies have not differentiated between
19 intentional versus unintentional weight loss--

20 DR. VAN HORN: Okay, this is just
21 an announcement to everyone. We have decided
22 due to technical difficulties today that we

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1 will go ahead and end our session and pick it
2 up again tomorrow morning at 9:00 a.m. Eastern
3 time by concluding the rest of this particular
4 report, and then picking up with the next
5 subcommittee report after that.

6 We appreciate your patience, and
7 we look forward to talking with you in the
8 morning. Thank you.

9 (Whereupon at 4:07 p.m. the
10 proceedings in the above-entitled matter was
11 adjourned.)

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A	
AARP 31:19	Achterberg 1:15
abdominal 82:1,6	54:19 66:10,11
able 8:20 34:8	68:19 94:7 146:1
54:18 59:15 92:12	149:11 151:4,11
128:16 169:22	152:8
182:1,3 200:17	acid 50:20 89:21
220:20 240:20	153:1,9 154:20
260:14	160:9 171:18
above-entitled	177:3 179:8,9
153:4 239:12	184:5 187:19
333:10	190:4 191:12
absence 51:19	193:21 201:1
absolute 316:6	204:3 207:12
absolutely 47:6,22	213:4,5 215:17,20
65:18	216:2,3,13 221:20
absorbing 87:15	222:12 224:20
absorbs 306:22	229:1,8,17
absorption 85:13	acids 3:5 37:5,15
Academy 250:4	153:13,16 154:12
269:17	154:12 155:8,14
accelerometers	156:7 157:21
311:7,10	160:6,10 163:7,9
accept 83:15	165:6,8,9 166:2
acceptable 289:8	171:2,7,11 172:22
290:3	174:17 175:1,10
accepted 45:8	176:12 177:2,11
48:18 76:2,12	179:4,7,12 180:2
78:5 168:18 330:7	181:13,21 182:11
access 243:15	183:18 184:12
accessed 11:8	187:5,15,17,22
accessible 16:21	188:5 189:16
accidental 312:1	190:16,17 191:3
accomplish 16:15	192:3 193:1
account 19:20	194:10,13 201:13
162:8 201:3	202:9,15 219:19
269:12	220:2,4,11,17,18
accounted 283:14	220:22 221:1,3
accounting 200:18	222:15,21 223:13
accuracy 192:3	223:22 224:2,16
accurately 115:5	225:2,5,12,13
282:10	227:14 229:4,6,8
achieve 46:3	229:8 230:10,13
237:14,19 322:16	233:18 234:3,7,16
achieved 193:15	234:19 236:20
325:9 331:11	238:11 290:6
achieving 99:1	302:7
	act 7:10,13
	acting 6:4
	actively 16:6 258:4
	258:9
	activity 20:17
	258:8 270:1
	304:13 310:17
	311:1
	actual 152:6 164:7
	315:13 319:3
	acuity 193:17
	194:2,20
	ad 102:2 118:18
	132:20
	ADA 117:19
	118:15 172:1
	176:7 279:17
	281:17 282:7
	285:2 286:22
	287:1,15 288:7
	289:21 290:15
	291:18 292:7,12
	294:14 295:16
	298:17 299:22
	300:9,14 303:4
	312:3
	adaptations 129:17
	add 51:10 94:8
	110:13 129:6
	152:17 170:10
	203:5 259:19
	264:13,18,19
	265:12 266:11
	310:21 313:3
	added 11:5 98:2,7
	98:11,15,21 99:21
	100:5 101:15
	103:1 104:20
	110:18 111:1,2,16
	111:22 113:2,3,5
	114:5 116:2
	117:16 121:13
	122:3 128:1
	132:17 135:8
	136:16 137:20
	138:6,17 142:20
	159:9 209:13
	210:3 230:1 247:7
	284:18 294:7,11
	315:9 316:19
	adding 86:12 87:5
	172:2
	addition 8:10 15:16
	16:17 146:18
	209:22 256:15
	258:6 273:19
	302:6
	additional 19:7
	119:8 163:1 166:6
	184:2 266:1
	address 12:18
	15:22 54:21 68:10
	85:3 99:9 116:9
	171:8,16 186:16
	202:3 204:4 238:8
	279:5 314:22
	325:20
	addressed 72:7
	73:16 135:21
	146:16 192:5
	220:2 221:7 240:8
	240:17 245:20
	268:14 270:11
	284:20 332:5,8
	addressing 77:16
	205:3 240:16
	268:12,17
	adds 258:17
	adequacy 16:2
	155:13,19 156:2
	186:17 203:15
	204:16 229:3
	230:21 233:20
	235:19 237:12
	251:7 277:4,11
	adequate 181:12
	230:16
	adequately 54:8
	273:20 280:15
	adipose 180:2
	304:3
	adiposity 73:14
	80:18 100:11
	250:18 255:15,18
	257:12 278:15
	279:8,13,21 280:6
	280:14 281:2
	282:1 283:15
	284:10,22 285:9
	285:20 286:3
	287:5,9,18 288:1
	288:4,13,19 290:1
	290:12,21 291:6
	291:12,16 292:1,6
	292:17 294:18,22
	295:7,13,22
	296:10,13 297:13
	297:18 298:7,11
	298:22 299:6,7,14
	299:18 300:7,16
	301:15,20 302:14
	302:16 303:2,10
	303:14,21 304:19
	305:4 307:7,14,20
	308:14 309:4
	316:4
	adjectives 209:10
	Adjourn 3:7
	adjourned 333:11
	adjust 280:16
	282:4
	adjusted 235:17
	284:6
	adjustment 196:7
	Admiral 6:1 9:6
	adolescents 118:22
	119:6 250:6,10
	251:14 278:18
	283:20 296:1
	297:15 301:21
	302:2 303:22
	304:20 306:10,16
	323:3
	adult 67:13 142:10
	adults 23:19 39:8
	39:13 42:18 44:12
	67:3,6,19 68:9,11
	68:12 71:2 98:6
	99:18 100:1 103:8
	117:22 118:16
	146:20 160:15
	205:22 221:10

245:18 246:5,11 248:4 249:14,18 249:21 250:19 251:10,16,20 254:7,11 255:22 256:12,19 257:1 257:12,21 258:2 261:5 267:13 276:8,22 302:12 311:21 314:15,18 318:6,22 319:15 320:6 321:11 323:3 324:19 331:20,22 332:9 332:13,16 advanced 31:3 advantage 39:10 43:16 advantages 330:9 advertised 322:17 advertising 274:11 advice 7:12 189:7 advise 201:18 adviser 6:7 advising 323:4 advisory 1:6 4:15 6:11,22 7:9,11 8:13 9:1,12 13:20 14:13,16 15:11 20:16,18 154:20 advocate 199:14 affect 108:16 118:18 132:18 134:2,21 135:9 155:9 259:1 affirmation 92:13 afternoon 268:10 age 205:2 206:1 221:10 250:8 276:9 286:9,10,15 289:9 321:7,8 332:9 aged 303:22 331:22 Agency 270:6 agenda 3:2 4:8 15:15 145:2 ages 19:15 99:8	285:16,17 ago 52:20 63:9 96:17 139:12 172:8 agree 61:22 68:15 88:5 92:11 115:15 122:19 127:18 137:4,16 138:18 139:4 140:21 141:10 169:8 203:12,21 218:5 219:5 225:10 309:15 315:21 317:7 321:17 agreed 16:16 19:18 318:14 agreement 19:1 22:8 199:7 Agricultural 5:11 Agriculture 1:3 4:8 10:7 Ah 237:21 AHA 48:13 ahead 63:2 145:15 210:18 226:1 276:5 333:1 AHRQ 270:7,8 272:1 273:9 aid 121:10 134:6 AJCN 88:17 al 211:14 304:12 ALA 180:4,7,9,15 180:16,16,16,18 182:3 183:1,4,5,6 183:17 Alexandria 4:4 allow 120:19 174:22 allowance 232:11 allowed 262:14 allowing 306:21 alluded 51:13 all-cause 180:19 almond 208:18 almonds 206:18,21 208:12 209:5 alpha 179:7,8	alter 31:12 127:10 Altman 278:11 Altogether 147:13 America 1:1 113:9 American 72:9 113:21 136:6 160:21 226:5 250:3 269:17 315:14 Americans 4:19 9:18 14:19 94:22 113:1 243:14,15 255:8 amino 37:5,15 302:7 amount 47:8 57:22 60:12 65:13 76:8 90:5 104:1 106:20 125:10 146:5 149:18 150:21 167:1 178:2 215:3 217:10 222:21 224:20 230:2 231:6 245:10 248:17 290:18 316:15 amounts 40:16 45:4 79:1 86:3 98:14,16,17 115:3 182:5,5 213:5 214:10 229:22 231:8,10 234:22 235:12,14,16,22 237:9 238:5 307:22 analyses 20:22 36:19 58:20 99:12 160:4 192:14 207:8 analysis 5:19 61:6 75:15 77:15 79:19 108:3 117:3,20 138:3 139:19 143:14 176:8 193:12,22 237:22 238:8 283:14 analyzed 26:15,16	Anand 4:5 and/or 23:13 130:21 184:3 295:11,20 300:15 301:18 animal 18:17 23:10 24:18 26:10,19 27:6,11,19 28:1 30:10 31:7,10,11 32:14,16 33:19,22 35:2,20 36:12 37:3,10 46:6 48:8 56:17,21 57:5,9 57:15 58:22 59:16 62:4,14 63:6 64:18 120:13,17 123:18 124:11,16 126:6 215:13 227:2 animals 120:19 announce 22:11 announced 7:17 announcement 332:21 Ansel 216:4 answer 21:1 73:16 128:15 202:2 227:19 267:22 answered 20:10 anybody 47:2 84:20 85:2 112:6 apparent 46:13 178:7 228:8,14 apparently 178:6 appear 282:11 322:15 appears 314:2 APPEL 1:15 56:13 57:8 58:2 59:2,5 61:3 64:9 116:6 122:5 123:5 125:8 126:14 137:18 138:14 139:10 140:21 141:20 144:10 166:19 168:10 170:1 187:1,14 188:1,4	188:19 189:13,18 196:8 202:18 203:6 216:18 218:5,14 219:2 260:10 261:20 263:16 264:7 310:11 311:9,15 316:11 appetite 130:22 269:21 apple 132:16,17 apples 132:16 applications 227:2 apply 17:11 66:4 appreciable 224:1 appreciate 26:2 28:7 50:18 54:3 54:13 55:8 131:17 134:10 186:13 196:21 198:16 333:6 appreciation 9:15 153:21 approach 19:18 21:11 61:1,6 83:11 199:15 265:15 approaches 17:8 approaching 76:22 appropriate 20:15 22:1 247:6 322:12 approximately 172:19 174:10 224:4 APRIL 1:10 archive 11:8 area 3:4 22:18 24:22 44:5 58:9 80:22 90:10 92:9 122:9 132:1 136:4 149:4 150:9 159:9 166:16 167:4,6 197:2,3 225:11 261:17 308:21 areas 40:15 178:6 180:2,13 241:14 242:15
--	--	---	--	---

argue 260:18 313:3 313:6	assistant 9:8	285:19,22 286:2	authors 106:9 109:1	260:21 263:13
arm 17:22 101:14 103:18 109:14 110:6	assisted 160:2	286:21 287:3,6,17	availability 241:13	267:22 291:19
arms 124:20 125:13,22 126:13	associate 131:19	287:20 288:11,15	241:19 242:11	295:16 298:18
ARS 2:1	associated 30:11	289:22 291:4,8,10	243:7,9,13 244:9	303:5 313:1
article 99:10 106:11	74:15,17,21 75:7	291:16,17,21	245:1,13	324:18 332:7,8
articles 18:18	79:15 80:19 107:7	292:2,3,16,19	available 13:8,10	backed 189:2
25:22 30:12 31:14	118:7 160:6 165:6	294:16,22 295:5	16:20 18:1 19:3	background 69:20
32:20 34:3 35:4	172:22 175:17	296:9,12 297:3,12	38:21 39:18 86:7	180:8 241:4 266:6
36:2 40:2 41:17	176:20 180:9	297:14,16 298:15	98:18 144:2 220:8	266:10 278:16
42:20 43:18 44:2	183:5 193:19	298:16 299:3,4,13	230:3 243:9	backwards 190:14
44:15 62:6 68:21	194:18 195:22	299:15 300:5,5,11	330:16	196:1
73:17 74:5 75:14	202:5 212:15,17	300:12,15,17,18	average 93:8	bacon 53:2
79:18 119:8	221:21 242:8,12	301:1,4,7,9,14	172:21 174:11	bag 173:22 180:22
130:18,20 218:19	242:16,18 244:7	302:13,14 303:9	175:16 224:3	baked 229:14
296:3 298:19	244:11 249:15	305:14 307:6	227:10 237:16	baking 224:18
301:11 327:1,22	253:7 255:3 262:8	319:7	265:19 289:7	balance 3:6 16:1
329:2	268:21 269:7	associations 23:19	avoid 51:15 61:12	24:13 44:5 62:4
artificial 123:20	272:6,10,15,18,21	27:21 48:1 107:21	327:17	98:5 100:11 101:7
artificially 119:22	274:1,4 278:14	176:14,16 304:15	avoiding 325:8	103:22 104:11,15
122:3	279:12 284:21	assume 53:1 56:22	327:20 331:10	106:17 113:10
asked 33:15 56:8	285:8 287:8	162:4 165:20	aware 92:10 162:6	118:19 128:17
73:8 98:2 106:7	288:18 290:12,20	190:15	261:10	137:3,11 193:7,9
184:17	292:5 295:12	assuming 234:14	a.m 1:11 4:2 153:3	199:17 239:19
aspartame 119:11	296:19 299:6,18	assumption 55:17	153:6 333:2	279:10 302:8
119:13	303:2 305:1,8,10	189:22 209:15	A1C 161:13	310:20
aspect 245:13	305:19 306:9	assure 7:11	<hr/> B <hr/>	balanced 102:14,17
aspects 55:19	307:14 315:8	assuring 184:11	B 1:19	104:9 113:13,14
260:15 314:20	325:21,22 329:9	ate 276:9 320:7,11	baby 196:3	131:4 213:10
assess 105:1,2	330:21 332:13,17	attached 145:12	back 8:2 19:10	215:4
280:15 281:11	association 27:6	attempt 192:21	25:10 42:11 44:21	barbecued 55:3
282:4,10 314:17	28:22 29:1,2 31:9	326:14	48:11 49:16 54:20	Barr 298:3
assessed 225:1	35:1 37:1 47:20	attempted 45:13	57:12,19 58:20	base 65:11 209:16
235:19 283:14	64:17 71:3 72:9	54:7 80:7	72:14 73:17 76:15	231:7 235:22
284:6 304:18	83:22 98:6,19	attempting 51:22	99:7 103:3 112:1	236:4
assessment 110:22	99:18 100:2 109:5	162:8	130:17 144:7	based 6:15 20:2
263:19 282:9	120:3 147:3,22	attendees 11:15,19	153:8 154:22	30:18 40:13 46:16
314:3,7 316:3	148:17 155:1	attending 13:4	155:22 175:19	46:20 65:12 70:4
assessments 115:14	174:1,4,5 180:16	attention 191:14,16	185:22 188:10	76:5,9 83:20
assignable 20:5	186:5 193:12	193:15,16 196:19	190:9 195:8	84:10 90:1 99:5
assigned 268:22	244:16 248:1,1	197:6 317:13	196:22 197:5	100:19 113:11
284:12	249:16 253:14,22	attributed 213:1	200:17 205:21	135:20 145:10
assistance 12:9	254:1 271:8,11	271:16	211:1 215:16	147:12 172:1
	273:11 275:7	at-risk 211:2	216:3 221:8	178:19 180:1
	276:15,22 280:5	audience 11:4	238:18 239:9	185:7 187:11
	280:13,14 281:1,3	Australia 28:5	244:1 245:7	194:11 195:2
	281:10,22 282:2	Australian 43:3		211:9 217:17,19
	282:11 284:8	author 116:9		220:19 221:4

224:9 234:12	beneficial 54:10	24:13 71:4 98:8	94:8 95:9 101:11	56:15 67:2 70:4
268:16 269:1	161:11,18 169:21	98:14,20,22 99:10	122:6 134:2 139:9	71:4,7,9 73:13
270:5,12 280:8	200:22 212:22	99:19,22 100:3,6	149:19 185:18	74:22 80:17,20
284:4 285:1 288:4	233:19 318:17,18	102:7,11 103:20	198:5 199:16	81:16,22 82:12,16
290:14 291:1	benefit 11:5 87:6	105:14,16 106:12	201:4 207:9	89:4,7 98:8 100:3
293:8 295:14	178:15,16 181:22	107:7,15 108:6,18	214:15 216:21	100:14 103:1,12
299:20	187:9 199:16	109:7,8,10,19	217:21 218:12	103:21 104:1,8,17
baseline 125:12	200:2 211:17	110:20 112:18	222:13 238:9,15	104:20 105:5,14
232:11 305:4	275:2 304:6	113:16,20 114:3	241:3 264:8	105:16 106:20
basic 220:1	benefits 23:17	114:16 115:4,5,11	267:21 283:5	108:1,16,18
basically 73:20	38:19 46:14 62:7	115:17 116:11	314:19	111:18 117:18
134:19 147:18	70:22 72:6 84:3	117:2 118:6,21	black 31:4	119:9 120:9
167:3 230:8	87:10 95:19	119:3,5 122:3,13	Blakely 153:22	121:19 130:10,21
basis 111:14	163:13 166:6	122:22 125:11,14	blanket 274:11	138:16 139:20
169:13 170:21	193:19 201:4	128:22 129:5	blanks 56:7	140:2,6 162:9
183:19 197:15	209:1 210:15	134:14 138:11,16	blood 27:8 35:3	240:10,22 241:1
207:12 265:5	212:17 213:10,16	138:21 140:8	38:13,14,15 39:5	242:10 243:2
281:6 282:6	213:20 214:10	142:19,21 284:17	39:8,8,14 41:13	244:4 245:19
329:22	217:2,6,9 233:8	290:10,12,20	41:15 42:1,14,16	246:9 247:13
Bazzano 147:19	323:1,17	291:5,11,22 292:5	42:18,18 43:4,5	248:11,16 249:11
bean 132:7	benefit-to-risk	293:6,7,10 294:10	44:10,13 45:5,8	251:4 253:3,5,6,8
beans 132:9	200:10	294:20 295:7	46:8 47:21 58:5	253:20 254:2
beautiful 185:17	Berkey 304:12	302:1 311:18,19	58:21 59:7,11,19	255:4 256:8 257:3
becoming 220:5	best 10:15 50:6	312:8 313:2	60:4 67:1,2 74:15	257:7,22 258:5,7
beef 29:14 53:19	64:20 80:8 126:22	315:10 316:17	75:8 79:5 88:1	258:9 259:1,3,12
229:13	126:22,22 144:2,6	317:1 318:11	156:15 163:15	276:12,14,20
began 21:18	259:16 271:7	beyond 84:6,13	168:21 173:20	283:19 296:19,21
beginning 25:20	315:12	169:18 179:14	206:9 212:5,8,8	297:3 305:2 316:9
54:16 78:15 83:15	better 17:7 48:8	205:1	289:20	324:3,7 325:3,7
88:22 100:9	59:15 78:4 90:18	bias 17:7	blue 106:2	325:18,22 331:5,9
131:11 332:15	90:18 116:1	biases 158:13	BMI 82:11,12	bottom 26:14 28:21
behalf 4:13 9:10	139:15 140:4	big 27:1 63:19,21	120:12 242:5,17	106:1 133:2 236:7
153:16	149:8 178:3	126:18 137:10	242:19,21 286:18	236:17 286:14
Behall 81:13	202:17 258:12	228:1	288:1,2 293:3	287:19 291:17
behavior 245:16,17	259:8,13 311:4,8	biggest 59:7	304:2,17 305:2	298:13 300:6
247:15 277:21	328:8	bioavailable 302:4	324:21 325:21	bought 55:17
315:13	between-group	biological 223:20	332:13,15	BOWMAN 2:1
behaviors 240:9	273:4	biologically 178:8	board 49:14 89:2	boys 248:2 254:4
245:6,19 259:22	beverage 102:2,12	biomarker 169:8	105:6 114:7 192:1	bran 88:2,6
Belarus 275:11	102:13 111:5	biomarkers 161:21	193:2	Braund 2:4 6:4
believe 85:17	116:20,21 117:2	173:19 193:18	Bob 190:7	Brazil 11:20
104:10 136:2	120:1 123:8,10	220:12 221:20	bodies 197:14	bread 86:1 305:9
195:3 196:20	124:22 129:19	227:5 330:10	body 19:17 23:21	break 47:1 79:11
238:11 259:15	137:22 142:4	bit 29:7 30:4 32:9	24:1,3 26:13	85:2 148:8 152:21
267:17 308:19	143:13,15 292:17	33:17 34:9 35:12	27:10 35:20,21	239:7
315:11	294:17 311:20	35:15,17 40:21	36:1 38:15 39:11	breakfast 246:1
believes 148:17	beverages 23:20	41:6 43:10 54:11	43:15,18 44:9	251:4,12,16,21

252:7,16,20 253:2 253:4,7 254:2 257:3 267:13 275:22 276:7,9,13 276:19 277:6,10 277:17,22 278:3 breast 26:11 27:13 31:7,10,12 32:5 41:5,9 64:19 154:19 191:4 194:5 195:1,21 196:3 270:22 breastfed 273:8 breastfeed 269:15 breastfeeding 268:5,13,20 269:7 269:8,13 270:15 271:8,14,16,22 272:6,10,15,22 273:10 274:1,3,6 274:8,9,12 275:3 275:8 brief 20:13 238:14 briefly 17:12 21:15 bring 117:15 142:11 144:22 204:12 bringing 50:22 234:2 British 184:20 broad 113:11 181:11 184:4 broadcasting 10:20 broader 76:7 128:4 210:13 broadly 17:11 broken 267:7 brought 8:2 96:10 Brownlee 82:8 building 176:7 builds 270:8 built 244:21 bulk 307:1 bullet 190:13,18 bundling 203:2 buried 316:18 busy 287:13	butter 207:17 216:1 buy 241:6 B-12 237:6 305:20 B-6 305:20 <hr/> C <hr/> C 305:20 CAC 34:14 calcium 295:10,11 295:20 296:10,18 296:20 297:2,4,5 297:6,13 298:6,10 298:22 299:5 300:15 301:18 302:4,5,21 305:22 308:12 calcium-supplem... 297:7 calcium/dairy 296:12 297:17 309:3 calculation 111:2 123:2 call 175:22 183:3 189:9 221:2 234:7 252:9,11 318:13 called 16:22 220:16 caloric 109:10 118:5,9 130:12 162:6 213:11 229:12 231:21 257:1 279:12 calorically 290:11 290:19 292:4 294:9,19 calorically-sweet... 290:10 291:5,11 291:22 292:16 294:17 295:6 311:18 calorie 46:18 102:17 106:19 108:11 111:14,17 111:21 112:1,2 116:4 118:4,6,20 130:15 131:3,12	131:14 133:12 157:10 170:21,21 214:12,16 231:7 231:17 247:3 255:10 263:18 316:21 325:4 326:14 331:6 calories 36:15 44:6 62:9,12 70:2 86:22 87:5 90:14 94:13 98:16 101:20 102:14 104:10,12,13,16 108:4,7,8,9,10 110:11,13 111:12 111:20 112:3,5 113:3 114:12,16 116:3,10,11 120:7 120:20,22 121:19 124:5,6,14 125:10 126:9 127:12 128:10 129:1,7 131:8,10 132:5,5 133:14,15,15 134:5 155:15,16 157:10 170:10,11 179:10 213:18 214:17 215:8 224:20 229:5,6,9 229:16,22 230:1,3 230:5,6,13 231:12 232:1 241:20 247:7 248:19 263:22 264:11,12 264:14,18 266:3 284:17 289:3,13 289:17 294:3 295:1 307:3,18 316:15,16,18,22 317:10 318:5 319:8 322:7 326:2 328:19 330:8 calorie-restricted 118:17 Canada 11:21 cancer 25:11 26:12 27:14,15,20,22	29:10,11,19,20 30:9,11,16 31:3,7 31:11,13 32:6 41:5,7,8 47:18 48:1 50:15 63:6,8 64:7,16,19 95:3 172:8,12 332:4,11 cancers 27:12,13 31:2 39:3,22 63:18 canola 167:16 capture 57:16 carbohydrate 16:2 23:8,16 60:6 61:11,19 70:19,20 93:2 100:10,15 105:4 115:14 142:15,17,18 156:19 161:6,18 161:20 163:2 289:3 324:12 325:17,20 326:1 326:11 327:5,7,17 328:5,15 329:7,9 329:19 330:20 331:3 carbohydrates 3:4 22:15,19 24:6 47:3 70:13,16,18 71:10 73:4 85:1 88:21 89:2,3,12 98:1 100:11,13,18 105:1,2,5 110:22 111:8,13 114:7 124:14 135:13 140:2,5 157:13,13 157:14 159:3 166:3 237:1 320:12 322:15 326:8 328:19 carbohydrate-de... 34:12 carbonated 293:9 carcinogens 55:10 cardiac 172:22 175:18 180:10,20 180:21	cardiovascular 26:12 27:8 33:20 34:1 72:19 73:11 74:13 75:4,6 78:18 79:6 84:2 93:18 95:17 96:6 149:22 154:9 156:12 158:1 159:6,7,15,22 160:8,14 162:16 162:22 163:2,10 164:13 165:2,7,14 165:22 166:4,13 169:14 171:13,14 171:19 172:6,13 172:16 173:3,19 173:21 174:12,13 175:11 176:17 177:17 178:10 180:14 182:12,18 183:20 184:13 206:8 208:4 209:7 211:12 215:14 220:13 221:12 225:14 227:6 233:6 329:10,20 330:22 332:3,10 Care 270:7 careful 152:3 214:16 320:16 carefully 201:9 222:22,22 Carole 2:1 5:18,20 carried 313:16 case 36:10 37:7,19 50:14 89:16 114:19 176:15 179:20 198:12 204:2 206:18 211:9 222:19 223:4 249:8 252:17,19 262:10 cases 19:2,9 20:13 32:4 302:13 case-control 103:6 categories 28:17 31:2 112:3 130:6
--	--	--	---	---

148:9 273:3	239:17	charters 7:3	286:3,9,15 287:9	232:2 233:1,1,4
category 30:7	Chairman 171:5	CHD 40:18 157:16	288:4,19 289:6,17	237:3 286:12
32:11 53:2 55:2	challenge 49:20	211:17	290:2,13,21	289:20 306:9
57:7 150:21 310:6	115:1	CHD/MI 212:15	291:16 292:6	cholesterol-raising
caught 60:5	challenging 185:15	cheap 243:19	293:1,2,12,17	155:12 215:18
causal 164:12	185:20	cheaper 267:2	294:11,18,20	216:12,14 229:3,6
causality 120:4	change 54:16 83:11	cheese 37:4 241:21	295:7,13,22	230:9,12
causation 169:20	88:14 116:19,19	cheeses 229:13	296:11 297:5,14	choline 232:10,18
cause 100:6 118:11	144:6,14 157:15	Chen 109:6	297:22 298:7,11	233:3
119:2 176:13	157:18 169:22	Cheng 304:18	298:22 299:8,19	choose 51:14 247:2
262:12 263:5	187:7,13 231:14	Cheryl 1:15 54:20	300:7 301:20	247:3 249:2 255:9
causes 196:4	237:1 245:16	55:9,12 65:14	302:1,12,17 303:2	chose 221:18
causing 106:14	259:1 265:1	66:10 93:15 94:7	303:11 304:8,14	chosen 192:16
caution 170:12	268:13 271:9	96:7 136:11,13,17	305:6 306:2,6,10	279:5
188:5 256:21	272:21 276:18	145:17,19,22	306:14,16 307:7	Chris 315:3,21
cautionary 46:20	304:4,7 305:9,11	149:1 152:14,17	307:15,17,20	321:22 323:21
caveat 311:12	308:22 312:9	Cheryl's 56:3	312:22 314:2,15	Christine 1:20
Center 4:6,11	changed 52:18	chew 306:20	314:17 315:6,14	66:20 68:13 96:17
cereal 74:12 75:5	82:11 141:11	chicken 229:14	317:2 318:1,3,21	142:7 201:14,16
80:10 85:22 95:5	143:14 194:6	241:22	319:19	205:6 278:7,9
95:11,12,14,19,22	231:13 236:15,16	chickens 30:3	children's 294:6	308:5,7,8 309:16
96:3,6,13	241:5,12 265:4	child 260:1	chime 65:6 205:6	317:21
certain 28:1 35:15	279:2	childhood 24:12	China 11:20 28:6	chronic 18:5 26:6
49:17 60:12 63:12	changes 6:14 36:17	37:8 99:8 275:1,8	43:6 50:1 148:7	38:2,10 40:4 74:8
66:18 145:10	45:20,20,22 54:17	278:15 284:14	chocolate 155:5	158:10 164:20
178:1 317:1	89:6 116:14	305:19 308:13	205:17 210:19,22	225:15
certainly 54:5	135:10 162:5,12	309:4	211:17,20 212:4	circle 29:2 54:20
129:11 169:12	169:10 180:10	children 68:4,22	212:11,14,19,22	circles 30:21 32:3
177:6 191:20	194:8 232:15	71:5 91:19 96:18	213:5,7,13,16,18	40:22
192:11 196:7	237:2 265:9 271:6	96:19 117:22	214:17 215:12,21	circumference
197:20 198:15	273:5,14,22 297:4	118:22 128:20,22	216:12 217:1	82:13
202:14 203:21	303:10 305:1	129:5,17 148:13	218:4,9 219:9	cite 319:6
204:20 214:20	changing 325:9	194:3 205:22	chocolates 219:10	cities 263:3
219:11 225:9	331:11	245:18 246:5,11	choice 46:14 85:21	clarification 52:10
226:22 232:7	chapter 15:21 16:4	249:6,14,18,21	234:17	190:8
cetera 60:14,14	16:7 51:12 69:19	250:6,7,16 251:9	choices 127:10	clarify 54:12 243:5
157:15,15 159:20	69:22 70:11 73:4	251:11,19 252:2	155:13,19 229:2	257:8 319:17
168:5 190:3	89:1 121:14 146:7	254:11 256:12,18	230:20 259:20	clarity 271:21
207:13,18 208:6	149:12 203:16	256:22 257:9	cholesterol 3:5	classes 234:11
213:3 314:16	240:18 245:10,11	261:5 275:3	39:13 44:12 77:13	classified 271:2
317:15	263:10 266:20	278:18,22 279:2,8	88:2,3 153:9,13	273:2
chain 169:20	chapters 15:4	279:13,18 280:6	153:17 155:10,14	clear 13:16 27:2
181:20 194:13	137:6 145:8	281:2,19 282:12	155:20 165:11,11	35:1 47:11 55:12
chair 1:11,14,14	Chardigny 223:5	282:17,21,21	169:22 208:7,7,14	67:17 95:8 107:21
13:19 153:10	charge 6:12 240:19	283:2,6,8,10,11	208:15 216:7	117:4 200:9
240:10	charges 221:18	283:20 284:1,2,10	230:6,18,22 231:6	213:11 306:17
chaired 22:16	chart 20:6 220:18	284:22 285:9	231:8,11,11,18	317:16 322:11

clearly 13:14 50:3 150:21 181:15 189:22 198:20 219:12 224:13,16 228:9	176:6,10 179:19 180:11 193:7 196:16 206:20 211:8 247:10,20 248:5 250:20,20 280:11 285:15,17 303:8 304:19 305:5 317:4 319:5 328:2 329:4 330:16	85:10 86:5 94:16 94:22 104:13 113:3,21 114:13 114:13 130:3 139:20 140:4 145:7 162:18 167:17 194:3 200:8 202:1 238:6 240:12 261:22 263:13 266:15,18 267:22 316:14 317:3,15 322:10	14:1,4,7,14,21 15:14 16:5,16 19:4,16 20:16,18 22:8,10 23:3 24:11,12,14 63:21 66:3 71:18 81:8 89:8 91:10 92:17 93:14 104:11 136:2 137:4 140:19 146:17,18 148:16 153:10 185:8 270:4 274:10 313:10	complementary 37:11 323:11
Clemens 1:16 54:3 91:16,18,22 92:11 151:22 152:14 154:17 191:7,10 195:13 196:5,20 197:18 198:15 201:14 202:11 203:21 204:22 219:6,21 226:7,15 226:19 227:11,18 228:4 309:16,22	cohorts 19:5 28:4 32:21 34:4 35:5,8 39:5 46:9 49:20 53:9 55:22 69:9 75:15 107:4 207:20 285:14	comes 50:19 64:14 88:22 94:11 106:18 129:16 135:15 151:1 167:18 196:12 200:20 289:17,18 294:6	committees 7:11 65:6 277:6	complements 240:17
clinical 54:18 58:14 61:7 116:14 158:15 163:3 164:16 184:3 196:15 208:4 210:8 224:22 285:12 286:1 303:8	cola 102:4,4 119:18 119:19	comfortable 186:6 264:13,15	Committee's 8:18 268:19	complete 7:13 15:1 37:6,8 225:5
closely 222:13,14 closer 4:20 264:5 closest 116:15 CNPP 2:1,4 5:10 5:20	cold 85:7	coming 10:4 95:12 95:19,22 205:8 234:20 266:17 267:5 317:10	communications 7:5	completed 10:4 117:21
cocoa 212:4,11,13 212:19 216:1	collaborator 5:5	commend 146:3	community 191:17 201:17 220:7	completely 33:12 43:11 57:13 115:15 126:4 321:17
cognition 194:2 cognitive 194:20 cohort 25:12 30:10 30:13 31:8,14 32:15 33:21 35:4 40:2 41:16 42:21 43:7 58:7 61:5,9 62:20 64:19,21 75:9 77:17 79:13 79:20 80:9,21 83:1 84:12 93:10 93:14 94:4 114:4 116:13 134:12 143:2 144:15 163:21 166:7 167:1,6 173:10,22	collaborators 5:12	comment 8:9 54:4 70:7 92:20 166:22 184:9 195:12,17 200:5 216:19 313:1	common 162:14	complex 322:14
	colleagues 192:5 275:12	comments 8:7 21:5 25:3 56:14 65:15 69:17 117:10 131:17 152:15 167:11 219:11 224:12 225:16 238:17 308:7	comparable 98:4	complexities 125:9
	collection 150:11	comment 8:9 54:4 70:7 92:20 166:22 184:9 195:12,17 200:5 216:19 313:1	compare 62:13 63:7 103:4 105:22 121:15 130:19 187:3	complicated 109:15 135:3 227:12 255:12
	collectively 38:22 39:19	commend 146:3	compared 36:13 62:4 63:10 77:2 82:17 84:18 86:1 98:13 102:10,15 103:10,16 104:2,5 109:7 110:7 119:13 132:8,8 207:20 235:20,22 293:4 306:6 330:11	comply 7:14
	college 276:9	comment 8:9 54:4 70:7 92:20 166:22 184:9 195:12,17 200:5 216:19 313:1	comparing 109:9 126:3 166:11	component 213:19 217:2,5
	colon 47:18 48:1 50:15 64:16 172:12	comment 8:9 54:4 70:7 92:20 166:22 184:9 195:12,17 200:5 216:19 313:1	comparison 101:16 117:1 125:7 149:15 167:21 196:10 210:14	components 37:9 46:11 155:7 186:11 190:3 309:19 310:3,4
	colorectal 26:11 27:12,20,22 29:10 29:11 41:7	comments 8:7 21:5 25:3 56:14 65:15 69:17 117:10 131:17 152:15 167:11 219:11 224:12 225:16 238:17 308:7	compounds 150:3 213:2	composition 152:6 154:19 191:4 194:5,6,9 207:12 238:2 310:4 318:7 322:17 330:12
	column 49:4 80:3 106:8 236:3,8,13	commercial 241:7	comprehensiveness 152:19 308:10	concentrated 136:9 302:3
	columns 236:8	commercially 86:7	concentration 223:2	concentrations 306:10
	combat 46:19	commitment 10:1	concept 15:22 52:8 66:1 133:4,13 215:18	concern 45:10 120:17,21 122:6 124:11
	combine 37:15 288:6 299:22	committee 1:6 4:16 4:17 5:15 6:12 7:8,9,10,20 8:2,8 8:11,13,17,19,22 9:1,12,14 10:11 10:22 13:14,20	compensations 110:19	concerned 113:17
	combined 176:17 287:12 292:10,11 292:21 295:15 300:4,13,20	comment 8:9 54:4 70:7 92:20 166:22 184:9 195:12,17 200:5 216:19 313:1	compensation 130:12,16	
	come 15:6,11 22:8 25:20 46:15 48:9 59:1,19 66:1 76:4			

113:19 318:9 320:5,13 concerns 62:10 76:11 86:10 concert 250:13 253:17 concise 14:16 conclude 94:18 107:21 concluded 271:12 273:9 282:7 298:5 299:5,16 301:12 concluding 333:3 conclusion 15:1 21:3,14 26:21 27:20 30:8 31:8 32:14 33:20 35:1 35:22 38:17 39:17 41:14 43:15 44:10 52:6 64:11 67:18 68:10 72:16,17 74:11,20 75:4 79:13,17 95:1 98:12 99:3,20 107:13 118:3 126:16 131:2 134:21 136:1 137:19 138:14,17 139:21 141:14 142:15 147:1 148:15 160:1 161:10,16 164:22 165:4,17 168:16 170:7,16 172:17 175:14 178:1 179:15 182:15 186:1,7 187:3,5 187:10,18 188:7 188:20 196:13 202:20 209:3 212:16 214:8,14 216:21 217:7 218:16 219:3 223:19 228:7 242:4 246:7 248:13,16 262:11 266:17,21 268:20	273:6 274:3 280:2 280:8 284:3 285:6 287:7 288:16 290:17,19 292:3 295:4,18 303:7 310:15 317:20 318:8 319:22 320:1,19 321:18 325:4,19 326:4,13 331:6 332:12 conclusions 15:8 16:11 19:17 20:3 21:16,16,22 22:9 27:3 47:13 63:5,7 64:12 65:17 81:9 105:11 106:10 113:19 118:15 131:21 136:22 137:2 146:17 170:3 187:16 214:12 217:17 262:7,18 270:5 299:19 concurrent 279:3 conduct 113:8 conducted 21:19 72:10 86:9 134:22 148:7 150:10 198:21 199:2 270:14 273:17 275:11 279:14 280:20 confer 213:16 confirm 275:13,14 conflicting 130:14 confluence 238:22 confounders 196:17 201:10 269:4 271:21 273:19 confounding 50:11 confounds 133:13 confuse 192:21 confusing 29:17 confusion 61:13 congratulate 308:10	Congratulations 47:8 connect 92:19 93:5 conscious 66:2 consciously 188:11 consensus 15:6,11 conservative 66:12 consider 15:7 37:11 94:14 108:7 128:20 287:11 317:11 considerable 107:14 149:13 consideration 21:8 considered 18:6 19:8 53:11 74:8 76:17 78:17 130:21 205:13 245:11 292:9 298:1 consist 290:3 consistency 19:21 33:10 65:13 93:1 192:1 261:4 consistent 28:16 32:8,19 33:12 35:16,18 36:21 41:12 43:11 56:5 78:6 83:10 84:11 91:12 93:3 95:16 110:3 135:16 137:1 138:12,22 139:6 142:12 192:19 197:4,9 199:12 221:14,19 224:13 246:11 249:13 267:14 272:17 273:5 312:6 318:5 323:13 consistently 96:7 constant 114:12 150:4 235:13 constantly 145:8 constituents 50:2 225:3 constraints 265:17	constructed 232:21 consume 37:10 97:4 98:13,15,16 111:7 114:15 120:20 201:19 222:16 224:9 241:6 249:1 251:20 283:10 302:17 307:17,21 315:7 317:14 326:7 consumed 39:10 40:15 43:17 46:5 75:11 119:17 136:9 149:18 207:17 218:10 241:15 246:16 248:19 consumer 265:19 consumers 54:6,10 201:21 207:20 220:6 259:20 consuming 94:21 94:22 112:17 114:16 193:20 226:18 236:18 consumption 74:16 79:14 98:20 100:22 107:6 114:21 120:1 125:12 128:21 131:3,19 133:11 147:5 148:18 155:1 170:18 171:10,17 172:12 172:18 174:8,16 174:22 175:5,9,15 177:10,15 179:3 182:11 194:7,8 199:18 200:11 204:20 205:20 207:15,21,22 208:3,11,18 209:4 209:19,19 210:21 212:14,18 217:8 218:1,17,21 220:10 228:13	242:9 243:8 246:1 251:4 252:8 275:22 276:7,13 276:19 289:10 294:1,19 contact 8:15 12:5 contain 150:2 213:6 237:5 302:9 containing 187:21 192:8 contains 193:1 201:17 Contaminants 238:1 contemporary 264:9 content 48:15 83:10 219:12 contents 231:18 context 51:18 61:12 150:7 contextual 317:5 continually 14:9 continue 7:17 8:13 9:18 19:13 21:7,8 174:21 177:9 continued 5:10 continues 10:13 continuing 4:17 continuously 286:11 contrast 47:16 50:8 125:16 271:9 contribute 107:15 108:10 129:10 283:18 289:19 contributed 320:8 contributes 120:16 186:10 contributing 294:8 contributions 4:18 94:16 225:7 259:8 278:12 contributor 263:6 control 22:21 36:6 43:19 44:6 80:5 99:2 110:11
--	---	---	---	---

111:11,21 121:8 131:8 135:1 158:14 159:12 161:22 163:12,21 164:8 173:9,16 175:3 177:13 201:9 211:9 249:9 257:17 260:15 261:1 269:3 271:20 273:19 286:13,18 293:12 304:4 controlled 19:5 36:16 42:20 44:2 44:16 45:19 61:17 62:3,15 66:14 73:1 74:19 75:16 78:10,12 79:16,21 80:13 84:14 103:11 108:5 111:14 122:11 124:9 131:11 158:15 179:20 181:9 192:13 206:3 211:7 212:7 269:2 270:10,13 286:6 291:9 292:13,20 296:5,7 296:8 300:2,3,22 303:19 308:17 325:5 327:12 328:11 331:7 controls 7:14 119:14,15 293:4 convenience 242:20 244:16 conversation 199:6 converse 37:18 conversion 181:7 182:8 convert 181:19 converts 183:17 convey 9:15 convinced 321:10 convincing 295:19 cooked 53:13 55:16 cookies 116:2	cooking 27:16 55:19 180:5 cooperation 5:10 coordinate 251:6 coordinated 203:19 core 164:19 289:11 293:18 294:2 corn 102:13 111:9 coronary 39:2,21 48:14 173:1 222:9 231:2 correct 54:2 151:4 170:17 190:18 199:10 252:14 260:5,6 correctly 264:11 correlational 169:12 corroborate 223:12 cost 7:14 113:21 counseled 86:6 count 26:4 44:22 45:3 104:10 105:11 110:20 114:2 140:9 265:15 counting 52:16,16 111:6 countries 95:3 96:19 97:4,5,7 149:5,16 279:20 country 95:13 96:4 167:14,17 180:6 180:13 224:17 couple 30:22 33:6 63:9 109:18 112:10 147:7 193:10 254:3 264:4 265:18 course 87:5 157:3 193:2 205:3 207:16 238:7 278:15 covariants 200:19 201:8 cover 19:11 205:16 260:9	covered 57:2 285:1 covering 154:10 156:4 co-executive 5:21 6:9 crappy 139:14 cravings 129:20 created 219:10 credible 95:16 criteria 17:11,18 17:19 18:10 19:7 19:19 20:2 158:6 158:9 163:16 171:22 192:19,20 205:20 211:1,4 221:9,11,15,16 271:4 272:2 285:4 290:16 critical 5:4 224:5 cross 36:10 41:18 106:2 203:8 299:20 crossover 43:20 81:3,14 102:9 103:6 132:19 cross-over 102:1 cross-section 282:20 cross-sectional 18:22 19:2 25:17 25:19 36:7,8,22 39:6 41:16 42:21 43:9,20 44:17 45:21 46:9 63:15 68:18 73:21 81:4 81:6 82:14,15 99:12,15 101:5 106:4 139:2,15 140:15,16 142:1 143:18 144:13 158:12 163:19 172:5 193:3 206:2 211:3 246:6 275:6 279:18 281:20 282:13 287:10 292:8 299:1,9 326:5	cultural 267:7 current 6:16 9:19 89:11 224:3 230:4 235:8 265:2 282:8 currently 181:4 213:19 217:1 289:6 cut 53:13 112:4 121:19 124:6 144:13 CVD 34:19 75:10 77:15,16 171:12 171:18 175:11,18 176:12 179:4,5,13 182:13 183:15 188:21 C-O-N-T-E-N-T-S 3:1 <hr/> D <hr/> D 232:13,19 233:3 237:6 daily 101:15 132:14 257:1 266:2 289:7 302:19 dairy 57:1,4 225:3 293:19 295:10,11 295:20 296:10 297:13 298:6,10 299:7,13,17 300:16 301:18 302:11,18 308:13 309:18 310:3,4 dairy/calcium 301:14 dark 212:19 215:21 219:9,10 data 19:3 20:22 22:4 25:7 31:20 32:9 38:4,22 39:7 39:19 40:6 42:17 43:10 49:6 52:4 55:6 61:10 62:19 65:9,13 67:3 68:11,17 72:12 76:5,8,14 79:7	81:7 83:1,17 84:1 84:7 89:1 90:1,18 91:14 93:13 94:3 95:3,4 101:2,3 105:3,7,9 107:2,2 111:7 115:8,12 121:22 123:17 124:1,2,11,16,17 126:6 128:20 129:8,13 133:20 133:20 134:2,7,8 134:11 136:14 138:10,12,19 140:7 141:18 142:9 143:10 144:3 146:6 150:11 157:5 169:16 189:4 191:22 197:4,9 198:7 204:1 213:13 219:8 220:8,19 226:11 226:20,21 233:8 233:21 234:13 256:2 257:14 275:1 279:17 282:15 283:14 294:14 315:2,18 322:8 327:19 database 8:9 16:21 238:2 databases 196:11 dataset 40:5 datasets 81:15 Davis 2:1 5:18 day 11:17 45:7 66:7 79:3 108:21,22 124:6,15 125:5,15 134:16 147:17 155:21 172:21 174:11 175:17 178:11,14 185:11 198:6 227:19 230:22 232:1,3,22 233:5,18 236:12 237:15,20 250:11 256:15,16,21
--	---	--	---	---

days 16:15 103:13 200:8 249:20	definitely 62:1 92:6 96:5 128:2 130:2 137:13 144:21 186:6	description 107:11	290:7 295:3	52:7 70:5 86:12 101:15,16 102:4 102:15 103:8 104:6 110:7 112:4 113:1 115:4 118:18 119:19 120:15 121:15 122:22 131:19 133:18,19 150:8 156:19,19 160:21 161:7,7,15 171:18 180:1,8 186:11 191:20 199:14,14 200:13 209:6 213:8,20 217:2,11 222:17 225:8 226:5 229:9 232:21 233:1 246:2 263:17 286:12 302:5 305:18 314:3,8 316:3 318:9,10,16 320:17 321:1 322:7 325:6 326:8 328:5,6,7,9 329:19 331:8
deal 189:14 191:14 191:16 197:6 331:18	definition 76:2,7 77:5,9 78:1,7 216:9 254:21	descriptive 62:5	Dewey 270:6,11,12 271:2 272:4,19 273:6	
dealing 61:4 122:13 167:1 201:8	definitions 76:12 255:6 256:17 259:13 271:22	deserts 241:14	DGAC 5:22 6:10 6:19 7:3 14:1,21 18:21 21:4 22:4 25:5 73:16 98:10 130:11 248:13	
deals 187:4	DeJongh 296:22	deserves 259:4	DHA 183:17,21 194:9,14,22 195:20 198:6 204:21 232:14 234:7 235:22 237:14,20	
dealt 184:18 196:17 203:14,16	deli 53:11	design 40:7 60:7,14 66:16 101:13 107:1 110:10 131:10 158:11 162:4 247:16 255:6 261:8 271:19	DHA/EPA 185:8	
death 173:2 175:18 180:20,21	deliberation 6:19	designated 5:20	diabetes 26:12 27:10 32:13,15,18 39:2,21 41:1 47:17 48:1,3 49:2 50:15,21 51:5,8 51:16 64:20 73:12 74:18 79:12,16 80:9,11 84:2 143:13,18 146:12 146:15 147:4 148:3,19 149:10 149:21 150:16 151:8 156:9,12,22 157:4 159:8,9,18 160:8,15 162:15 162:22 163:3,10 164:16 165:2,16 166:1,13 170:4 206:11 233:7 332:4,10	
debate 169:11	deliberations 7:22 13:16 239:3	designed 28:20 53:5,18 102:21 126:22 196:17 222:22 223:1 243:7 308:16		
decades 278:19 279:3 289:6 313:14	delivery 293:5	designs 25:22 66:19 73:18 74:3 88:21 132:1 133:10		
decided 20:11 99:6 332:21	demarcation 323:2	desirable 174:18		
deciding 77:8	demonstrated 283:12	desire 257:21		
decision 25:10 72:8	DeMoura 75:22	desserts 317:11,14		
decisions 71:17	dense 170:11 231:20 251:21 320:17,21	detail 75:19 282:19		
decrease 174:2,12 242:1 253:5,20	densities 115:18	detailed 107:11 166:20 168:11 264:22		
decreased 81:16 162:21 289:5 293:13 304:2,9 307:14	density 137:2 162:6 215:7 242:19 244:13,15 307:3 307:13 308:1	details 16:19 17:4 286:4 298:8		
decreases 160:13 165:11,14	Department 1:3,4 4:7 5:5,13 9:9,16 10:2,6,8	detect 273:21		
decreasing 133:12 208:14,15 293:9	departments 6:14	detected 271:11		
dedicate 148:22	dependent 219:13	determine 177:13		
dedicated 4:22	depending 45:1 46:16 82:22 102:19 132:21 140:12 332:15	determined 256:17		
deep 9:15	depends 53:4 269:8	determining 149:8		
deeper 244:20	deplete 184:21	detrimental 223:21 323:19		
defense 87:18	deputy 4:11 6:4 9:7	develop 14:15,18 177:10	diabetic 160:17 161:22	
defer 145:21 152:10	derived 46:5 154:16 171:17 188:3,4 217:16	developed 10:14 174:21 259:14	diabetics 51:7 156:20 161:8,19 162:14	
deficiency 181:18	Desch 212:4	developing 4:18 136:5 157:4	diagnosed 18:13 26:7 74:8	
deficit 310:20	describe 21:15	development 5:2 6:21 10:5 147:3 193:17 194:21 202:16 286:19	diameters 212:2	
define 54:7,11 83:9 83:19 152:3 254:16 267:3	describes 20:7		diastolic 42:1,6	
defined 54:9 243:6			diet 15:22 20:22 37:10 51:12,15,22	
defining 52:11 251:21				176:8 180:16 188:12 189:12 192:22 194:13 198:19 201:22 221:8 224:14 230:21 240:9

242:9,13 244:5,7 244:11 245:4 259:2,6,9 278:14 279:1,6 281:13 282:9 284:20,21 285:8 287:8,18 288:18 296:18 297:4,6 302:19 303:1,10,13,20 304:1,6,13,16,16 304:18,21,22 305:3,8,17 306:8 306:12,15 307:6 307:10,11,12,18 312:13 314:5 315:7,7 317:20 320:1 321:20,21 325:11,12,17 326:11 327:17 331:13,14 332:6	31:5,21 32:4 33:8 36:14 41:4,8 42:4 42:6 43:3,5,7,8 44:1,3,7 63:16,20 64:12 65:11 75:10 75:21 77:14,17 78:21,22 81:21 82:1,6,13,16 85:11 100:17 101:18 102:3,16 103:12,22 104:13 110:6,13 111:10 111:15 131:6,12 132:6,9,13,16,21 135:11 150:15 182:7,8 192:17 223:17 254:4 266:13 270:22 271:16 273:4,21 297:1 326:15,20 329:14	241:15,17 245:19 254:16,17 259:9 261:15 262:20 264:1,4 273:2 285:16,17 316:4,7 319:14 321:11 323:3 differential 51:6 differentiate 220:3 differentiated 223:14 225:19 287:21 332:18 differently 33:15 34:10 38:7 55:5 57:16 133:4 262:21 differing 236:19 326:16 330:11 difficult 36:15 45:2 99:16 101:11 102:18 103:14 110:19 121:7 123:4 126:2 131:1 138:19 145:4 166:11 168:3 178:7 254:15 256:6,7,14 314:17 325:13 331:15 difficulties 12:5,15 332:22 difficulty 101:6 149:14 dig 267:21 digestibility 152:6 digestible 98:1 124:13 digestive 72:20 dilute 143:22 Ding 211:14 direct 116:18 117:5 directed 193:16 direction 168:6 169:6,21 191:18 252:6,13 254:8 directions 127:17 261:19 directly 265:21	281:7 317:4 director 4:6,11 5:18 6:2,5 disadvantage 244:6 disadvantaged 242:14 disconnect 58:3 65:3 discounted 107:16 discourage 250:6 discouraged 294:21 discrepancy 139:7 discretionary 112:2 230:2 289:13 294:3 discuss 15:12 240:12 310:19 314:22 discussed 16:8 60:10 63:22 181:6 181:15 269:9 270:10 discusses 314:6 discussing 69:21 228:20 discussion 18:21 70:1,2 73:4 96:9 115:7 137:12 148:21 149:13 152:10 166:18 171:3 176:1 184:17 203:3 205:12 209:14 210:16 218:15 225:17 238:14,17 238:22 239:2 263:10 308:7 discussions 3:4 16:12 22:18 65:6 154:3 204:12 208:20 213:2 disease 6:2,5,8 9:8 18:5,12,13,16 19:12 26:7,13 27:7,8 33:20 34:1 38:2,11 39:3,22	41:8 48:14 72:19 73:11 74:9,14 75:4,7 78:18 84:2 93:18 96:6 149:22 154:9 158:10 159:6,7 160:8,14 162:16 163:3,10 164:13 165:2,7,15 165:22 171:13,14 172:13,16 173:1,3 173:19,21 174:12 175:12 177:17 180:6,10,14 182:7 182:19 206:8 208:4 209:8 211:13 215:14 220:13 221:12 222:10 225:14,15 227:6 231:2 233:7 329:11,20 331:1 332:3,10 diseased 156:12 diseases 5:8 40:4,7 49:17 50:9,13 74:10 159:22 164:20 171:19 181:19 182:12 dish 53:20 displace 293:6 disputing 142:14 dissect 167:22 disseminated 63:9 dissolved 132:5 distal 29:20 distances 242:18 distilled 279:16 distinction 311:17 distinctions 210:11 distinctive 114:22 distinguish 281:4 distribution 193:14 213:4 218:18 234:12 308:22 distributions 166:14 215:20 disturbing 317:12 dive 244:20
Dietetic 72:9 dieting 121:4 diets 51:6 70:8,10 95:10 103:5,6,10 103:11 104:7 127:6 162:10 167:22 192:7 195:10 238:8 288:21 306:18 324:12,15 326:17 326:19 327:5,6,7 327:8,9 328:16,18 329:7,8,9 330:4,6 330:11,12,13,20 331:3 diet-related 5:8 differ 130:15 difference 35:12 41:7 60:4 104:16 126:1 220:15 222:10 223:15,21 270:20 286:17 293:14 304:10 310:20 312:16 318:20 321:9 327:15 differences 27:15	different 26:17 28:10 29:7,19 30:18 31:1,1,2,4 31:12,21 32:9 33:9,11 36:4,12 40:8 43:12 44:8 45:2 49:9 50:3 55:5 63:18,18 64:7,13 66:17 75:18 76:22 78:3 78:21 79:1 83:21 95:21 97:16 100:18 101:10 102:11,16,21 103:5 104:7 107:1 107:1 108:6 109:4 109:11,16,18 111:8,17,19,22 115:2 117:19 131:15 132:1,12 133:2,10 148:8 149:16 150:3,5 151:17 171:8 180:7,8,12 203:20 213:15,16 236:3 236:10 240:1			

diverse 207:9	70:15 85:4,17	201:11,14 202:7	draft 22:7 26:21	EAL 118:15
divide 239:21	86:17,19 87:1,8,9	202:11,18 203:4,6	27:1,2,20 30:8	earlier 10:19 51:13
divided 229:22	87:16 88:5,15	203:10,21 204:7	31:8 32:13 33:20	65:21 202:14
Division 5:19	89:8,18 91:16,17	204:10,22 205:8	35:1,21 39:17	208:9 272:16
doable 232:8	91:18,21,22 92:1	213:22 214:1,2,4	41:14 43:15 44:10	281:17 298:17
document 220:3	92:11,14 93:6	214:5,7,8,19	65:17 72:16 74:11	314:11 331:2
275:1 322:9	94:5,7 95:2,7 96:5	215:1,6,9,10,15	75:4 79:12 80:18	early 14:21 121:12
documented 17:5	96:16 97:3,19	216:16,18 217:14	99:20 118:3 131:2	216:4 278:19
documents 7:6	112:9,12,13 114:1	217:20 218:5,7,11	134:20 138:17	earned 280:21
dogs 32:10 52:17	114:9,10,17,18	218:13,14,20	147:1 148:14	easier 110:20
53:8,10	115:6 116:6 117:9	219:2,5,6,15,21	160:1,5 165:4	easily 11:7 77:2
doing 28:16 71:18	117:12 122:5,19	225:17,20,22	172:17 175:14	122:14 126:18
83:16 99:5 123:14	123:5,15 124:18	226:2,7,13,15,16	209:3 212:16	322:1
125:19 126:19	125:8,20 126:12	226:19 227:8,9,11	216:20	Eastern 152:22
264:16 308:21	126:14 127:2,13	227:15,18,20	drafted 22:4	239:9 333:2
DONALD 285:17	127:21 128:3,7,8	228:4,15 233:11	drafting 21:21	easy 66:6 122:21
dose 96:14 178:2	128:13,18 130:1	233:13,15 238:13	149:11 174:15	eat 55:15 62:11
185:17 219:3	136:18,20,21	238:19 239:14,17	drafts 15:4	89:12 90:3,12,14
doses 45:9 80:15	137:8,16,18 138:8	239:20 240:14	dramatic 278:16	90:17 94:14 105:8
199:2 224:5	138:14 139:3,10	252:15,18,22	DRI 93:19 330:13	124:12 125:5
dose-response	139:22 140:21	253:1,6,11,13,15	drilled 196:14	128:10 131:9
116:18 117:5	141:6,8,9,20	260:6,8,10,20	drink 100:22	133:9 134:3,4
119:21	142:6,13,22 143:6	261:20 262:1,3,19	101:16,17 102:15	178:14 181:17
dose/response	144:10,16 145:5	263:2,6,7,8,14,16	107:22 108:21,22	218:4 246:12
271:13	145:17,19,21	263:21 264:7,15	109:21 121:15,15	247:2 250:1
double 26:4 44:22	146:1 149:1,11	265:11 266:9,12	129:5 134:15,16	251:11 320:2,20
45:3	150:13 151:4,5,11	266:15 267:6,8,9	drinks 101:15	eaten 241:10 266:1
doubled 11:18	151:22 152:8,14	267:10,12,16	102:17 109:4	306:21 322:14
278:22	152:15 153:7,11	268:2,4,9 274:15	110:3,4,7,8	eaters 50:12 228:1
doubly 281:8	153:14 166:19	274:17,19,20	115:22 125:15,15	eating 46:16 61:15
doubt 67:9	167:8,12 168:2,10	275:5,17,18,20	135:8	63:19 86:14,22
Dr 1:11 4:3 6:4	169:1 170:1,2,14	276:1,6 277:3,8	driving 125:4	89:16 135:3
9:11 10:17 13:20	171:5 177:18,20	277:13,18 278:1,5	168:15	158:13 206:5
13:22 22:20 47:4	177:21 178:5,17	278:10 308:4,8	drop 178:9 188:2	241:7 243:8
47:6,7 49:5,19	178:18,22 179:1	309:5,11,14,16,21	189:15 217:11	245:22 246:2,8,18
50:18 51:3,9,10	184:7 185:5,13	309:22 310:7,11	dropout 18:1,3	249:2 256:8,11,20
52:9,13 53:3,22	186:15,20,22	311:3,9,14,15	dropping 198:8	256:22 257:4,11
54:2,3,19 55:8,11	187:1,12,14,20	312:2,7,9,11,17	DrPH 1:16	260:1 265:3,8,19
56:3,9,11,13 57:3	188:1,3,4,8,19,22	312:20 313:11,13	drugs 201:13	277:6,22 315:13
57:8,11 58:2,15	189:13,17,18,20	313:15,18,22	due 46:10 83:8	315:17,19 318:2
59:2,3,5,12 60:8	189:21 190:7,11	315:22 316:11	332:22	320:4 321:13
61:3,21 62:21	190:12,19,22	317:7,8,17 319:1	duration 269:9	eats 93:8 196:2
63:1,3,10 64:9	191:1,10 195:7,13	319:4,16,18,21	271:14 272:22	248:18
65:5,19 66:10,20	195:15,16 196:5,8	320:15,18 321:16	durations 274:9	Ebbeling 291:9
67:5,15,17,20,22	196:20 197:12,18	321:22 322:3,5,18	_____	292:22
68:2,3,8,13,15,19	198:1,15 199:4,5	323:10,12,14,16	E	ecological 40:3
69:1,12,14,15,18	199:11 200:3,14	323:20 332:20	_____	113:11
			E 1:16 232:15	

economic 244:6	197:7	172:6 206:8	energy-balanced	equivalent 200:2
economically	efforts 243:12	208:20 210:8,8	112:15 209:6	equivalents 236:11
242:14	284:15	222:10	energy-dense 289:2	Eric 1:19 47:4
eco-friendly 174:20	EFSA 197:19	ends 126:21	engagement 8:12	52:11,21 54:13
177:9 184:10	eggs 30:3 33:18	energy 3:6 16:1	English 17:20	55:11 76:19 77:19
185:1	34:17 37:4 57:6	23:21 24:3,13	enjoyable 10:16	84:7 85:8 93:6
education 252:8	57:17 232:4	44:5 61:16 71:4,5	enormously 273:15	95:7 114:1,10
253:9,19 261:1	235:12 236:6,15	71:9 98:4,8 99:20	enrolled 305:6	124:18 142:22
293:8	eight 79:4 81:1	100:1,7,11,19	ensure 9:17 273:20	144:11 150:13
effect 20:1 40:21	179:18 211:7	101:21 102:7	ensures 17:4	153:19 154:13
44:11 45:10 59:10	235:2 244:8	103:9,11,17,22	entail 17:19	155:22 166:22
72:22 77:7,16,18	250:20 272:1	104:5,8 106:12,15	entailed 18:11	167:10 171:2,4
77:20 78:8 79:4	Eight-eight 101:1	106:18 107:22	entered 73:5	177:18 187:8
80:3,11,16 121:19	either 41:22 87:12	111:11,18 112:14	enters 9:14	191:11 194:17
130:15 131:13	92:12 103:19	112:16,19,22	entire 184:22	198:20 200:14
133:11 146:10	118:17 141:13	113:10,13,14,15	191:12 221:19	202:13 233:12
148:4 156:10,18	235:15 253:22	115:22 117:18	310:5	238:20 262:3
163:8 176:11	260:15 264:10	118:18 119:6,11	entry 181:11,20	317:17 319:2
177:14 182:22	300:10,21	119:13,18 120:16	environment 135:3	323:21
183:20 185:21	Electric 35:17	125:5 128:16	240:9,21 241:5	Eric's 52:2 54:21
201:1,5 216:11	electronic 16:21	130:10,21 131:6	242:3,6,8 243:1	ERS 265:14
220:9 223:3,12	elevated 18:4 39:14	131:18 132:14	243:11 244:4,22	especially 14:11
224:2,21 256:11	44:13 289:20	133:21 137:1,3,11	245:1 247:16	37:15 49:20 60:18
270:2 273:9,12	eliminated 224:16	142:7 160:4,11,21	259:2 261:14,16	61:12 62:9 98:22
274:5 296:20	226:5	164:4 170:11	265:2,10 266:21	129:16 139:17
301:2 302:11	email 12:13,18	224:7 228:7	environmental	152:9 175:3
303:20 305:16	emailed 12:7	231:17 237:1	258:22	181:12 242:9,14
310:5 325:10	emails 12:20	239:16,19 269:19	EPA 183:17,21	243:14 244:12
327:15 329:13	Emily 200:21	270:22 279:10,11	232:14 234:7	249:19,22 271:20
331:12,20 332:1	emphasis 6:20	279:12 280:5,13	235:21 237:15,20	283:20 284:16
effective 162:21	185:7 322:11,13	280:16 281:1,5,7	epidemic 14:12	294:14 314:5,11
274:12 324:13,15	emphasize 197:13	281:11,18,22	159:8 279:4	314:21 322:9
327:6,8,20 328:6	employed 126:22	282:5,8,10,16,22	epidemiologic	329:10 330:22
328:16 329:7	empty 284:17	283:3,8,11,13,15	157:16 160:3	essential 72:20
330:5	289:17 295:1	283:21 284:1,6,9	165:13	290:6 293:20
effects 39:12 42:8	enables 11:3	284:15,16 289:1,4	epidemiological	302:7
78:6 81:13 88:6	encouraged 247:3	289:12,14,16,19	76:16 77:22 83:5	essentially 26:4
166:13 184:14	247:5 248:22	293:17,21 294:4,6	84:7 93:15 100:4	72:12 169:5
205:19 207:15	251:20 255:8	294:7,8,12 295:2	105:12 107:5	173:18 179:12
208:17 210:21	256:19 258:3	302:2 307:3,13	111:4 120:10	318:1
212:22 223:21	302:17 307:21	310:13,19,19	121:5	Essery 67:15,22
240:8 259:5	endorsed 269:16	316:7 320:17,18	epidemiology	68:3 278:11
323:19	endpoint 89:7	320:20	48:13 184:14	establish 120:3
efficiency 12:22	164:5	energy-adjusted	equal 66:4 219:11	270:2
efficient 174:20	endpoints 35:9	304:16	equally 229:22	established 7:10
184:10 185:1	75:10 87:18,21	energy-balance	equate 185:11	164:11
effort 54:11 105:2	159:14 163:3,5	103:2	equivalence 236:18	establishments

243:8 259:21 265:3 estimated 238:6 271:5 293:21 estimating 40:13 estimation 265:15 estrogen 31:22 et 60:14,14 157:14 157:15 159:20 168:5 190:3 207:12,18 208:5 211:14 213:3 304:12 314:16 317:15 ethnic 267:7 Europe 28:5 50:1 European 197:14 197:22 evaluate 83:13 246:17 evaluated 73:1 76:8 evaluating 5:1 Eve 28:8 59:20 67:7,15,16 68:3 240:20 252:9 261:8 264:16,19 278:11 event 13:7 164:14 events 171:12 174:13 176:18 179:4 182:12 everybody 82:5 88:18,19 93:16 104:10 145:1 189:10 238:16 312:14 320:6 ever-so-important 5:2 evidence 6:18 9:20 15:2,19 16:11,18 16:19,22 17:3,13 19:17,22 20:14 21:15,21 28:3 30:9 38:18 41:17 44:18 48:4 50:7 51:20 73:22 74:16	75:12,13 79:13 89:14,15 95:16 99:4,21 100:4 106:14 107:6 117:20,20 130:11 130:14 138:5 139:5,7,14,16,20 141:1,2,3,6,7,15 141:16,22 142:3 143:4,9 147:2 148:15 160:11 161:4 162:1 165:9 167:6 172:2,9,11 173:5 176:3,4,7 179:6,14,17 181:3 181:5,9 182:16 183:22 186:3 188:20 189:10 191:8 193:5 195:2 196:12 197:16 198:11 206:13 207:10 209:15 211:10,20 212:20 217:15,16,17 222:1 223:20 224:1 233:17 242:7 246:10,11 246:17 247:8 248:14 249:13 251:11,13,14 255:2 256:10,10 257:20 258:6 269:21 274:2 275:5 280:2 281:17 283:10,19 284:8,11,13 285:5 285:7,10 286:22 287:2 288:6,7,17 289:21 290:13,18 291:10,18 292:2,7 292:12 294:13 295:19 296:8 297:11 298:1,6,17 300:21 301:6,8,13 301:17 302:15 303:11 307:9,19 309:7,12 313:8	315:12 316:10 318:15,19 319:10 321:2,10 328:22 evidence-based 25:9 evident 271:17 exactly 61:18 145:5 227:15 278:1 315:19 examine 183:13 192:12 222:12,13 226:22 309:18 examined 40:9 42:10 166:7 192:12 193:6 197:8 204:1 221:6 221:19 222:19 272:4 303:9 307:6 examining 201:22 example 52:2 58:6 96:22 150:2 282:18 314:4,6 exceed 289:7 290:2 exceeded 289:15 294:5 excellent 66:21 114:11 152:1 238:19 239:4 274:21 exception 18:20 138:22 247:22 248:6 exceptions 19:6 excess 229:21 231:21 excited 10:19 excitement 10:7,9 exciting 11:2 excluded 25:21 26:2,6 58:12,17 67:7,21 68:4,22 73:22 74:6,7 99:12,13,15 115:20 158:11 172:4 193:2 246:6 excluding 163:18 211:3	exclusion 17:18 18:10 192:20 221:16 exclusions 19:7 exclusion/inclusion 290:16 exclusive 270:15 272:6 274:8 exclusively 246:21 269:15 273:8 excuse 224:6 executive 4:5 exercise 89:19 200:7 321:6 exercises 155:11 exist 186:14 existing 35:22 167:22 182:18 exists 38:18 expanded 76:6 156:7 expansion 159:5 expect 36:16 44:7 60:3 86:13 101:21 106:19 110:14 194:21 207:11 254:1 expected 244:19 254:9 expecting 14:5 261:5 expenditure 281:7 expensive 243:19 experience 12:4 201:15 experimental 107:5 expert 20:5 expertise 9:22 197:3 explain 7:7 explained 270:21 explicitly 316:16 exposed 85:13 exposure 193:20 express 4:21 extended 303:5 extensive 21:20	extensively 269:13 extent 283:22 extra 108:10,11 111:17 112:17 265:21 extremely 157:3 <hr/> F <hr/> FACA 7:10,10 8:10 face 222:8 facilitating 13:16 facing 14:12 fact 48:7,15,16,20 51:11 54:14 95:21 128:20 129:2 149:15 173:11 176:8 186:13 194:12,18 199:2 204:2 216:14 220:8,14,16 221:1 222:14 223:14 226:9 233:16 241:6 314:14 317:9 318:16 factor 162:8 266:16 factors 134:21 168:18 183:3 209:8 260:17 279:6 315:4 failure 77:21 fair 58:8,9 95:9 121:7 166:22 185:18 195:12,13 245:10 fairly 29:5 30:1 32:8 38:17 45:6 57:22 65:9 80:15 81:15 86:4 88:3 105:12 107:11 110:2 111:1 137:1 245:2 251:18 264:22 familiar 116:7 family 206:14 260:2 278:13 fantastic 263:4 far 21:6 82:11
--	--	--	--	--

134:5 148:16	159:1 160:12,13	favor 200:11	93:14,17,20,20	36:18 269:11
239:6 307:17	160:21 162:7	favorable 162:11	94:4,11,15 95:4,5	275:15 297:20
farmers 243:16	165:10,19,21	208:17 209:7	95:9,10,11,11,12	finds 35:22 93:14
fast 241:9 242:19	166:2 170:20	favored 19:4	95:14,15,19,22	fine 66:8 91:4
243:6 244:14,15	205:14 215:18	favorite 173:11	96:3,3,6,12,14,18	189:14 201:1
246:12,14,15,21	216:7,12 229:21	FDA 54:8 76:2 77:5	96:21 97:11,16,20	214:7 255:7
247:2 248:7	230:1,5,7,11,14	78:7	132:17,19 135:5,6	finish 154:5 276:2
259:16 260:12,19	231:21 232:6	fear 170:8	137:1 303:2,10,13	Finland 28:5
261:17 262:8,11	235:14 284:18	feasible 174:18	303:20 304:1,6,16	first 17:13 21:17
262:13 321:13	289:18 290:4	feather 256:14	304:21 305:8,17	22:14 23:2,3,17
323:7	294:8 316:19	February 265:14	306:3,7,8,12,15	24:21 26:9 38:9
fasting 80:16	323:1,19	federal 5:20 7:9,18	306:18,19,22	39:17 56:14,16
161:12	fatty 3:5 50:20	10:6 14:17	307:2,4,7,10,18	73:5,10 75:3
fat 24:6 48:15,21	153:1,9,13,16	feed 227:2	307:22 312:13	76:15 77:4 79:2
49:12 50:19 71:10	154:11,12,20	feedback 13:1	314:5,7,8 315:7,7	101:13 106:17
82:1,6,12 154:8	155:14 156:7	feeding 38:7 61:17	320:14 322:15	118:16 146:3
154:15 155:1,12	157:21 160:6,9,10	67:10 158:18	fibers 94:19 135:8	154:7,10 156:9
156:11 157:6,12	163:7,9 165:5,8	192:15 260:2	field 76:21 95:17	158:5 172:14
161:3 164:4,13	166:2 171:1,6,11	273:3	259:4	177:7 190:12,18
170:18,21 213:9	171:17 172:21	feel 161:3 264:13	fields 204:1	198:9 199:15
215:12,13,22	174:8,17 175:1,10	267:18 277:14	FIFTH 1:8	205:1,18 228:22
216:2,10,11,15	176:12 177:1,3,11	feeling 65:22	figure 44:21 94:15	236:3 240:8 245:3
229:13 232:13	179:4,7,12 180:2	184:19 307:1	131:8 267:1	253:13 260:10
237:2,3 247:7	181:13,21 182:11	fell 168:7	final 15:9 27:3	262:6,17 279:11
284:20,21 285:8	183:18 184:5,12	felt 50:9 156:20	155:6 234:17	282:18 308:9
285:19,20 286:2	187:5,15,17,19,21	161:22 179:6	281:6 297:19	fish 37:3 57:4
286:12,12 287:3,4	188:5 189:16	189:10 205:13	302:22	172:11 174:8
287:8,18 288:12	190:4,16,17 191:3	214:21 301:5	finally 148:6	177:1,9 181:17
288:12,18,22	191:12 192:3,8	female 121:3	155:10	182:4,5,6 184:16
289:1,5 290:1,2	193:1,21 194:10	fermented 219:14	financial 243:17	184:21,22 185:1,2
296:19,21 297:1,3	194:13 201:1,13	fewer 62:11,11	266:22	185:10 186:8,12
297:4 302:18	202:8,15 204:3	65:10 86:22 90:14	find 25:16,17 27:5	189:2,6,7,19
304:16 305:2	207:12 213:4	107:12 128:10	62:2,16 64:7 74:4	193:20 194:6,7
306:4,4,5 307:12	215:20 219:19	177:2 250:11	75:9 92:12 95:18	199:17 200:11
315:8,9 317:20	220:2,4,11,17,17	286:11 307:3	101:8 103:14	201:18,19 202:14
318:3,5,7,9,9,16	220:21 221:1,3,20	fib 174:4	110:5 118:8	235:6 236:6,19
318:18 319:7,9	222:12,15,21	fiber 23:18 24:6	120:11 134:11	237:5,18 238:7,7
320:1,2,4,7,17,22	223:13,22 224:2	46:11 52:1 69:3	176:16 180:15	fish-derived 176:12
321:1,4,6,15,21	224:15,19 225:2,5	70:22 71:10 72:6	182:21 191:21	177:1
322:7,8,9,10,12	225:12,13 227:13	72:10,17,21,21	220:14 255:17	fit 53:2 92:22 112:2
322:21,22 323:7	229:1,4,6,7,16	73:6 74:13,21	273:3,6 281:10	113:16 128:2
324:21 325:17	230:9,12 233:18	75:6 80:19 82:21	314:20	131:18 134:7
326:11 327:6,17	234:3,7,16,19	83:3,4 84:1,4,6,11	finding 19:21 47:9	200:7
328:6 329:8	236:20 238:10	85:2 90:4 91:11	65:14 77:16	fits 198:11 199:21
fatal 176:17	290:6	91:13,14 92:7,16	180:14 275:13	five 20:9 24:2 42:19
fats 113:4 135:13	fat-free 229:13	92:18,19,20,21	315:6	125:15 146:22
155:2 157:20	fat-rich 103:7	93:3,8,9,10,11,13	findings 30:2 32:8	147:5,8 159:1,12

161:8,10 163:20 172:20 194:16 206:20 285:12,13 286:6 296:4,4 297:10,11 298:11 298:12 299:10,11 300:3,8 301:2 303:16 305:12 327:1 fix 319:2 322:1 flavonoid 211:19 211:19 flavonoids 211:16 flavor 287:14 flavored 129:21 Flint 77:18 78:1 91:5 flip 162:18 166:9 261:13 Flood 102:2 132:15 flow 212:2,2,8 fluid 242:1 306:22 focus 6:18 15:5 25:5 51:1 116:3 172:13 186:12 241:1 249:7 focused 51:5 56:18 67:6 147:8,14 156:18 159:6 198:17 206:17 238:10 246:4,20 293:9 focuses 323:6 focusing 116:2 146:20 149:12 158:3 168:18 170:19 171:11 173:15 245:15 317:13 321:3 322:20 folate 305:21 folic 89:21 follow 22:12 187:2 216:19 256:19 320:9 followed 69:9 82:10 102:9	132:20 154:13 326:17 328:21 329:17 following 13:17 17:18 257:22 258:5,10 follows 148:15 food 20:19 24:6 32:10 34:12 40:12 40:13 41:21 42:9 46:11,20 69:5 71:11 83:10 86:21 88:13 91:13,14 92:20 93:21 114:22 118:20 126:8,9 128:5 129:21 132:13,13 132:18,21,22 133:5,20,22 134:1 134:4,9,13 136:9 155:11,13,18 156:3 185:7 187:11 188:13 192:4,4,22 196:2 198:9,12,17 199:21 200:1,4,12 202:13 203:2,7,16 204:3 209:12 213:9,20 216:11 224:18 228:17 229:2,10,19 230:20 231:7,8,10 231:12,19 233:21 234:2 235:1,16,19 237:10 240:9,21 241:4,6,9,14,16 242:6,8,20 243:6 243:11 244:9,15 245:1,1,13 246:12 246:14,15,21 247:2 248:7,8,17 249:2 250:1 258:1 258:3 259:6,16,18 260:12 261:14,16 261:17 262:8,11 262:13 264:3,8 265:1,9,13,16	281:13,15 306:1,2 306:20 307:1 309:20 314:12 317:14 319:22 321:14 323:8 foods 24:3 37:9 46:16 54:9 63:13 63:18 71:8 72:18 85:22 90:12 97:17 98:14 115:3 118:6 125:4 127:7 130:9 130:13,15 133:7 134:1 135:5,6 136:7 147:9 155:2 166:15 170:10 171:11 205:14,14 206:14 213:6 220:18 225:7 229:20 231:9 232:17 241:13,15 242:11 243:6,13 243:18,18,20 247:5 249:3 255:9 256:20 260:19 267:2,3 284:16 285:20 287:4 288:13 289:11 293:18 294:2 302:1 306:19 307:2,4,22 317:11 320:2,4,7,21 321:15 322:13,15 food-based 6:21 14:16 15:8 forget 175:21 form 22:7 24:7 71:11 94:14 130:20 132:13,22 133:21 134:9,13 209:20 formal 20:12 21:4 183:22 format 168:9 forms 132:13,21 133:6 209:13 211:19 213:15 218:8 229:21	231:20 formulating 15:20 formulations 213:13 formula-feeding 272:12,17 forth 175:20 188:10 221:13 265:17 fortified 89:21 Forum 63:8 forward 10:3,13 54:4 69:16 83:16 172:3 315:11 333:7 found 20:7 31:13 35:2 36:2,13 37:2 43:2 47:19,21 50:21 58:1 63:14 63:19 77:6,7 92:5 101:17 104:6 121:14 174:1,1,3 174:5,8 176:11,13 180:9 186:5 236:22 237:13 244:3,5,8,13,14 255:14,15,22 271:7 272:5,9,14 272:20 273:22 275:7 280:12,14 280:22 281:21 282:2 285:18,22 286:2,10,16 287:2 287:6,16,19 288:2 288:11,14 291:4,7 291:9,21 292:1,2 292:15,19 296:8 296:11,14,16,17 297:1,11,14,19 299:2,3,4,12,14 300:15,16,17,18 301:1,2,3,3 302:13 303:19 304:5,15,20 309:6 326:6 327:3,5,7 328:2,4,7 329:4,6 329:8 330:18,20	four 23:22 41:17 43:18 44:15 79:17 101:14,17 105:18 107:3 109:5 110:5 111:20 125:15 158:18 159:20 163:21 164:2,21 173:8 176:5 179:18 192:15,16 206:5 234:6 235:2 235:4 236:9 270:5 270:16,17 276:11 276:18 280:9,10 280:11,18,19,21 280:22 281:21 298:21 299:2,9,12 300:16,19 305:13 327:7 fourth 13:9 14:20 281:9 fourths 302:5 four-year 50:5 Framingham 109:3 France 96:22 97:7 Frank 157:11 frankly 198:16 Fraser 270:9 free 12:6 85:18 88:13 114:14 120:8 150:22,22 French 147:10 148:1,2 151:1 frequencies 41:22 frequency 40:12 208:1 246:2 256:8 256:11,19,22 257:4,11 259:12 281:14 314:12 frequent 281:12,15 frequently 66:7 207:17 209:12 fresh 55:1 242:2 freshman 276:21 freshmen 276:8 Friedman 288:4 fries 147:10 148:1 148:2 151:1
---	--	--	---	--

front 56:16 144:22 255:16	future 11:6 162:17 166:16 174:15 182:2 271:20 273:18	getting 56:6 97:17 112:20 113:6 181:21	72:14 74:22 75:17 76:10,14 78:6 91:7 97:22 99:7 100:8 105:10 108:9 112:1,3,7 115:11,19 117:13 122:4 123:15 132:6,10 135:20 137:8,19 140:12 144:7 146:1 163:18 171:1,21 178:12 191:3 195:21 197:4 205:9 210:18,19 216:22 217:6 224:13 225:22 240:3 244:1 245:7 260:21 263:12 276:5 278:6,8 298:7 315:11 327:11 331:18 333:1	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11
fructose 102:13 103:16,19 104:14 109:19 111:9,12	G	Gibson 106:11	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	good 4:4 9:6 14:1 42:11 67:5 76:13 89:2 90:13 95:1 97:13 105:3 111:6 115:15 117:9,12 144:19 167:13 185:13 186:10 188:8 196:5 228:5 238:17 259:4 266:7 268:9 302:7 309:5 311:3,11 313:16 315:22 319:17 322:4 327:13
fruit 93:9 94:15,19 95:9 115:21 136:14 146:10 147:4,15 148:11 149:18 150:6,12 151:9 240:22 242:2,6 243:2 244:12	gain 71:18 98:21 106:15 107:8 109:20 110:15 115:12 118:9,11 119:3 121:11 129:10 246:13,19 275:3 276:10 297:6,17 300:19 319:7 320:9 324:22 325:8 331:10	girls 248:1 254:4 257:12 286:11 296:21 321:8	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	goal 86:20
fruits 64:4 94:2,12 96:8,11 97:2,15 146:14 148:19 149:13,17 150:15 150:18 151:2 241:21 242:10,12 242:16 293:19 320:10	gaining 124:13	give 8:20 75:20 81:8 84:8 88:12 89:5 90:16 99:13 112:14 126:7 129:14 136:12 185:18 224:11 230:15 232:8 287:14 318:21 321:12	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	goals 229:11 231:14
FUKAGAWA 1:14 52:9 127:2 128:3 128:13 225:20 226:2,13,16 227:8 227:15 239:14 266:12 267:6,9	gardens 244:10	given 20:3 43:13 79:2 81:20 85:20 86:3 134:16 149:13,15 150:1,5 159:7 166:14 173:3 233:7,16 262:9 274:7 319:11	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	goes 49:8 65:20 190:9 194:15 216:3 291:19 295:16 298:18
full 7:20 8:2 169:2 169:9 213:9 240:18 250:16 279:14	garlic 136:8	global 11:19	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	going 23:6 24:20 28:16 29:6,7 30:6 31:6,20 32:2,11 33:5,10 34:11,20 50:4,4 57:2,22 72:12 75:18 84:8 87:6 88:13 90:7,9 91:8 94:1 96:8 97:22 99:9 104:12 106:19 108:16,18 110:12 111:14,20 112:10 114:4 115:9,11 123:20 124:3,4 125:18 127:7 128:9 132:2 135:11 136:12 140:4 142:8 153:11,18 154:5
fuller 148:21	gastrointestinal 306:13 308:3	glucose 80:16 103:16,19 104:15 109:19 150:22 161:13,21 162:12 164:17 206:10 308:2	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	gotten 101:3
fullness 307:2	GC 187:8	glycemic 151:9 304:22,22	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	governed 7:9
fully 154:6	gender 36:18	glycoproteins 161:14	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	government 14:18
Fulton 281:9	general 17:10,17 30:20 32:2,7 33:16 45:4,9 108:3 132:22 135:5,9 148:3 156:16 166:21 206:15 207:2 208:2 210:14 228:11,11 233:8 248:18	go 23:7,16 25:10,15 26:22 29:4,16,22 34:15 35:7 38:2 42:3,9 44:21 49:16 54:4,15 57:12,19 58:20 59:3 63:2 70:2,5 70:13 71:14 72:1	154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	grade 20:3,5,7 27:8 27:9,10,10,13,14 27:17 28:2 30:12 31:13 32:19 34:2 35:4 36:2 39:3,6,9 39:15,22 41:16 42:19 43:18 44:14 48:4,5 50:17 55:7 56:12 64:14,15,18 64:22 65:3,8 66:15 72:2 74:15 74:20,22 75:11 80:22 100:1,7 118:14,21 119:6 138:5 140:20,20
function 306:13 308:3	generalizability 20:1		154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	
functional 72:21	generalized 135:2		154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	
funded 87:19 210:12	generally 17:19 18:10 39:4 41:15 46:8 66:18 88:7 135:6 164:3 207:18 212:9 307:2		154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	
Fungwe 154:1	generate 17:14		154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	
further 5:15 16:8 20:7 150:9 175:2 181:9 195:11 197:16 205:12 226:6,8 230:10,13 233:2 332:7	generic 57:10		154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	
	gentlemen 4:3		154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	
	German 304:19		154:10,14,17 155:4 162:18 163:18 169:20 171:7 195:8 200:5 200:9 202:19 203:7 204:15 205:16 217:13 219:17 230:9 238:2 239:21,22 240:16 247:17 261:22 262:2 264:19 268:7 275:21 277:19 308:21 319:9 321:12 327:11	

140:22 141:11,17 145:10,12 147:5 161:4 162:1 165:16 173:4 175:20,20,22 179:15 181:3 182:19 189:3,10 189:14 195:3,4 196:13 209:9 212:19 224:11 242:4,5 246:9 249:12 251:9,10 254:6 267:14 268:22 276:17,17 276:18 277:1,11 280:6 284:12 285:9 287:9 288:20 290:21 292:6 295:8 296:1 303:14 308:12,14 308:19 309:6 313:3,6 319:11 320:19 332:12	76:3,5,11,14,14 77:1,6,9,10 78:5 78:13,15,20 79:2 79:8,10,14 80:15 80:19 81:13 82:17 82:17,18 83:9,12 83:19,21 84:5,12 85:11,19 86:1,7,8 86:12,14 87:10,14 89:5,13,13,17,21 90:3,4,8,15,17 91:15 95:22 96:2 96:21 97:5,6,15 241:20 293:18 305:10 318:11	Greece 329:17 green 90:12 287:16 grill 55:16 grilled 55:9 grocery 243:15 ground 229:13 group 8:21 19:18 68:6 152:20 154:21 158:19 197:19,19,22 200:4 205:13 231:8 234:8 237:16,17 238:20 239:4 270:14,22 286:13,13,18 293:4,12,14 297:8 304:4	20:8,16 25:1 89:11 154:20 158:4 159:5 169:8 176:9 188:13 189:12 221:8 224:15 245:21 250:13 318:21 320:10 332:6	gutmicrobiota 136:3 guys 76:19 198:7 203:1	head 48:12 316:20 heading 169:5,14 head-to-head 167:10,21 health 1:4 5:5,7,13 6:3,6,8 9:9,9,16 9:21 10:2 14:10 23:11,13,17,19 24:9 31:18,19 33:4,7,8,17 38:19 38:20 40:19 46:14 57:1 62:7 70:22 71:2 72:6,11,20 84:17 98:12 101:1 135:19 136:3 146:11 147:19,20 149:22 154:9,19 155:3 156:13 160:7 162:14 163:13 164:6 165:6 166:6 177:14 184:14,15 191:5 194:19 195:18 196:1 199:18 205:4,5,19 206:7 207:14 210:10,15,21 212:17 214:10 221:18 224:2 259:2,7,10 269:16 270:7 290:5 324:9 330:10 331:21 332:2
graded 21:4,21 66:18 71:22 grades 65:16 66:13 81:9 grading 19:16 20:6 64:11 grain 71:1 74:12,14 74:21 75:5,7 76:8 76:18,20 77:3,14 78:2,11,16 80:10 80:19 81:17,19 82:4,4,21,21 83:2 83:3,3,4,5,9,13 84:1,4,4,10,17,18 84:21 85:3,9,21 85:22,22 90:5,10 90:11,19 91:3,6 91:11,21 92:4,8 92:16,19 93:8,11 93:14 94:4 97:21 304:21 grains 23:18 72:18 73:6,7,10 74:17 74:21 75:3,11	gram 111:20 178:14 185:19 289:3 316:6 grams 45:7 76:20 78:2 79:3 91:3,6,7 96:12 178:14 218:22 307:18 gram-per-gram 183:19 grant 152:8 granularity 169:4 graphic 193:13,13 grateful 10:12 gratitude 4:21 great 87:6 115:12 117:9 153:21 178:17 189:20 190:22 191:14,15 193:15 197:6 201:7 239:3 268:2 greater 107:6 131:20 151:2 174:22 179:14 192:18 206:6 243:15,17 266:22 270:16 276:10 283:21 284:2,9 285:8 288:19 290:19 305:19 307:21 326:19 328:17 330:7 greatest 301:7	growing 141:6 283:19 growth 69:10 290:6 295:3 Guenther 154:1 guess 63:20 67:11 90:22 93:15 109:22 126:14 128:13 136:1 139:22 151:5 168:16 176:21 187:20 188:18 317:18,20 guidance 5:19 15:18 129:14 191:19 323:8 guide 306:1 321:14 guideline 4:15 146:17 184:1 245:4 250:4 320:14 guidelines 1:6 4:19 5:3,14 6:11,15 8:12,15 9:12,18 13:19 14:19 19:14	habitual 296:17 Hakanen 286:8 half 89:12,13,22 156:5 216:13 289:18 halted 238:22 Halton 33:4 40:17 147:9 hamburger 29:15 hamburgers 33:7 hand 62:1 67:20 169:11 hang 199:13 happen 151:16 happened 265:10 happens 144:17 227:3 234:9 236:9 happy 65:15 140:19 189:9 214:6 254:17 276:18 hard 14:22 25:15 80:6 85:10 88:1 105:1 106:22 111:3 122:20 134:10 143:21 310:18 harkens 215:16 harvested 219:13 haven't 129:3 HDL 45:20,22 155:9 HDLs 223:9,9	hear 8:3 44:4 62:22	

66:6 68:1 89:19 98:5 139:11 225:20,21 239:3 274:18 277:19 heard 17:1 48:12 132:7 135:7 hearing 21:12 153:18 heart 39:3,21 41:8 48:14 58:11 59:8 60:18 61:18 77:21 109:3 173:1 180:5 182:15,20 222:9 290:5 heavier 118:10 heaviest 293:2 heavy 199:19 200:19 height 296:21 held 13:10 235:13 hello 239:20 268:9 help 22:12 28:7 52:21 59:20 65:7 65:14 67:8 77:19 84:8 91:8 93:7 114:1 115:9 128:11,12 134:11 216:15 219:18 254:22 255:9 265:8 322:16 helped 23:4 helpful 99:1 177:12 210:9 228:19 261:9 264:20 265:5 268:1 helping 26:3 helps 256:22 hemoglobin 161:13 HHS 2:2,2,3,4 6:3 6:9 7:2 9:4,10 Hi 116:6 high 37:7 45:6,9 57:21,22 60:1 62:11 70:9 78:17 96:14 98:15 102:13 103:17 104:3,4 107:17	111:9 125:12 135:5 136:7 155:2 156:19,19 157:3 161:6,7,14,18,19 161:20 162:10 170:11 174:16 205:14 211:18 213:5 215:7 216:10 233:6 234:6,11,16 245:2 278:3 285:20 287:4 288:12,21 302:9 306:17,19 307:2,22 320:22 321:6 324:14 327:8 330:4 331:3 higher 37:16 40:16 56:12 70:7 91:14 95:4 99:22 100:14 101:21 118:5,20 129:20 149:6 180:15 182:16 183:14 186:4 198:5 199:2,9,16 223:8 242:10,19 244:13,14,16 276:21 287:8 294:15 296:17 306:2,5,8 307:10 322:9,9,15 326:8 327:6 328:7 329:19,20 330:6 330:21 highly 85:8,12 302:3 high-density 262:14 high-fish 236:5 high-protein 326:19 high-risk 80:14 231:2 high-3 237:16 238:7 hindrance 311:1 historical 265:1,7 hit 316:19	HI3 234:8 235:5,5 235:8,9,11 hold 15:9 114:12 holding 117:11 HOLLY 2:2 home 5:17 9:14 11:1 241:11 249:1 249:3 265:13,20 266:2 293:5 Honduras 270:14 Hooper 212:1 hope 16:10 89:10 168:14 202:15 hopefully 84:7 93:6 192:14 Horn 1:11,14 13:20 13:22 51:10 60:8 65:19 69:15 97:19 117:9 141:6 145:5 145:19 152:15 153:7 238:19 274:17,20 275:17 277:18 313:22 317:8 322:5 332:20 hospitalized 18:14 hot 32:10 52:16 53:7,10 hour 156:4 239:8 hours 9:17 119:12 249:20 250:5,11 Hu 157:11 Huang 282:18 huge 134:18 146:5 178:9 273:16 human 1:4 5:6,13 9:10,16 10:2 17:20 98:12 124:17 humans 320:22 hunger 130:22 hungry 234:21 hydrogenation 221:4 hypercholesterol... 297:21,22 hyperlipidemia	74:9 hypertension 26:13 27:9 42:1,7 74:9 77:19,20 Hypertension/bl... 34:22 hypocaloric 324:12 324:14 328:15 330:4 hypolipidemia 231:3 hypotheses 149:20 hypothesis 126:12 303:12 hypothesize 95:20 hypothesized 279:7 <hr/> I <hr/> idea 55:9 75:20 84:5 90:2 188:9 230:15 317:12 319:17 ideal 162:9 ideas 315:14 identified 68:17 211:6 238:5 270:4 271:19 272:1 296:2 identifies 119:7 303:16 identify 231:11 identifying 268:17 II 20:4 27:8,9,13 28:2 34:2 35:4 39:6,16 41:17 43:18 44:14 48:5 64:14,18 65:12 66:15 74:16 75:11 100:1,7 118:14,21 138:5 162:1 173:4 175:20 179:15 181:3 189:3,14 195:3,4 196:13 209:9 212:20 224:11 242:4,5 251:9 254:6 268:22 276:17	277:12 285:9 287:9 288:20 290:22 292:6 295:8 309:13 313:6,20,21 319:11 332:12 III 20:4 27:10,11 27:14,17 30:12 31:13 32:19 36:2 39:3,9,22 42:19 48:4 64:15,22 65:8,12 74:20,22 80:22 119:6 147:5 182:19 251:10 267:14 276:17 277:1 280:6 284:12 296:1 303:14 308:14 309:7,13 320:19 immense 14:14 impact 24:2 71:8 94:18 127:10 129:11 130:9 150:16 155:12,18 156:1 183:14 194:4 205:5 209:7 215:11 226:10,12 227:4 229:2 233:20 237:12 309:19,20 impacted 69:11 impacts 149:21 157:18 225:11 259:2 implausible 280:16 281:4 282:22 283:3,8 284:6 implication 123:13 126:20 127:4,16 174:19 202:22 203:13,17 218:2 243:10 247:1 248:21 249:18 250:3 251:19 255:7 256:18 262:12,17,22 263:4 266:21
---	---	---	--	--

278:2 323:16	90:16 91:2 122:15	99:7,11,16 101:5	39:15 43:8 44:14	incredibly 317:5
implications 20:21	impressions 64:13	106:6 107:12,12	45:15 64:3,17	incumbent 220:7
37:2 46:2 48:7	impressive 56:16	130:18,20 139:1	65:10 110:18	index 82:16
50:17 52:5 56:18	improve 258:4	161:12 206:7	133:1 140:12	indicate 193:13
82:19 110:17	259:18 271:19,21	211:14 230:2	147:2 148:16	indicated 46:7
120:6 127:18	improved 88:19	279:18,20,21	251:14 255:2,20	198:20 228:8
129:19 130:2	159:22 160:7	280:19 281:19	277:15	indicates 107:6
133:18 137:20	161:21 164:4	285:11 286:5	incorporate 266:5	193:14 242:7
162:2,15 165:18	165:6 173:18,20	287:10 291:2	incorporates	299:17
170:15 174:14	194:18 195:22	292:8,13 296:3	145:10	indicator 169:14
177:5,6,7 181:4	242:13 330:10	298:20 301:10	incorrect 144:3	169:19
190:10 198:18	improvement	303:17 305:13	increase 61:13	indirectly 264:12
203:5 209:11	196:4 212:10	309:9 324:18	107:22 156:11	indispensable 37:5
212:21 214:21	258:14,15 304:2	332:9	177:10,15 181:5	individual 8:21
215:4 216:20,22	improves 160:16	includes 6:13 74:12	184:1,20 217:9,13	46:12 196:15
224:12 228:20	168:20 195:18	75:5 80:18 166:4	232:15 237:7	245:16 260:16,22
250:12 269:10	258:2,8	189:8 207:16	243:13 250:9	281:5 282:6
288:21 293:16	improving 164:22	221:11 224:20	252:16 253:2,3,4	individuals 8:14
310:14 311:13	212:5,14	231:20 307:12	253:7 278:17	11:10 18:4 98:13
316:14 317:22	inability 83:8,18	including 27:7,12	293:3 308:1	118:8,13 156:8
319:4,19 322:19	inadequacies 93:4	38:1,10,20 72:18	318:10	159:2 171:13
323:6	inadequate 22:4	98:7 99:21 100:5	increased 143:16	175:6,11 177:16
implies 123:14	310:22	119:3 146:14	143:17 161:17	182:18 211:3
importance 25:3,4	inaudible 275:11	156:13 193:11	175:5 180:18	234:18 248:22
70:7 77:11	311:21	206:19 207:2	194:12,22 195:20	326:9
important 6:12	incentives 243:17	224:10 234:2,10	208:2 223:5	industrial 219:19
13:16 21:2 37:9	266:22	242:11	232:16 235:2	220:4 221:3
45:11,14,16 48:16	incidence 30:12	inclusion 17:18,19	237:11 241:19	222:11 224:15
52:4 54:5 60:9	73:11,12,13 74:18	107:3 120:14	242:1,19,21	225:13 226:4,13
69:2 88:8 97:12	77:21 79:15 120:1	158:6,9 163:16	246:12 249:15	industrially 220:11
97:18 116:17	174:2 206:11	171:22 211:1	251:12,17 255:4	industry 52:18
129:16 137:5	incidences 18:16	221:14 271:4	279:8 285:7	210:12 224:18,19
154:3 156:21	include 7:4 25:5	272:2	288:18 290:1,21	247:4
166:16 169:4	36:10 59:4 97:14	inclusions 19:6	293:12 294:18,22	infancy 19:12
170:12 183:11	106:4 144:21	inclusion/exclusion	297:16 299:6,18	infant 191:5 194:19
185:3 191:13,18	180:18 206:2	285:4	303:14 304:1	195:18 273:2
200:15 202:4,16	229:20 237:22	income 241:14	306:1 315:7	infants 19:11 205:5
203:8,11 204:17	257:5 266:7	243:14 260:17	329:10,21 330:22	infarction 176:21
205:3 209:20	284:15 311:5	261:1	332:17	inflammation
210:1 215:7 219:8	323:15	inconclusive 142:2	increases 266:2	156:15 163:14
222:7 260:18	included 18:8	inconsistencies	269:19,20,22	165:13 166:5
266:7 269:6 270:1	25:22 28:11 34:4	29:12 63:13 64:8	increasing 46:19	168:14,15
273:13 288:2	38:5 44:18 54:22	110:21 137:13	69:5 70:8 141:7	inflammatory
306:12 316:13	57:6 58:18 62:2	inconsistency	156:2 233:20	159:16 162:12
317:6	63:15 68:5,7	63:21 255:5	306:22 332:14	169:7,10
impressed 11:14	69:13 73:19 74:5	inconsistent 9:1	incredible 47:7	inflection 178:21
impression 86:8	76:7 81:6 91:19	27:21 30:2 36:18	152:19 308:5	influence 128:22

154:8 259:11,16 259:20 260:1 influenzas 248:17 258:22 260:2,3 inform 14:17 information 8:16 12:4,7 17:11 36:9 94:8 140:10 148:13 212:9 217:19 310:8 informed 146:18 informing 6:13 ingested 307:1 initial 54:21 271:3 initially 270:4 initiated 15:20 input 65:18 insight 152:1 insights 200:12 instance 51:8 180:3 202:17 insufficient 172:11 181:5 183:22 256:2,10 298:5 301:17 303:11 307:8 insulin 80:17 152:5 159:20 160:16,16 164:17 206:10 intact 93:21 intake 23:10,20,21 24:3 26:10 27:6 27:11 28:1 31:9 31:11 32:16 33:22 35:2 36:1 37:17 38:1,9,12,14 39:4 40:13 41:14 46:3 46:7,19,20 64:21 71:1,3,4,5,9 73:10 74:12,14,20 75:5 75:7 77:14 80:18 83:2,3,3,14 86:21 88:4 93:9 94:10 94:16 96:4 97:8 98:7,8,12,21 99:19,20,21 100:1 100:2,15,19	101:21 102:7 105:4 107:14,17 107:22,22 111:11 111:18,21 112:14 113:14 116:14,21 117:18 119:11,11 119:13 120:16 129:1 130:10,21 131:6,13,14 132:14,18 133:6 133:12,21 134:1 136:5 142:5,7 143:16 146:13 148:1 149:2,6,9 150:12 154:18 156:10 161:17,18 161:19,20 163:8 179:8,9,14 180:18 181:5,12,13 182:16 184:1,5,21 194:13 210:5 213:11 214:16 224:3 228:13 233:4 241:1 242:6 242:9,13 243:2 244:5,8,12,12 253:2,4 258:2,3 259:2,7,9 264:3 266:2 277:10 278:14 279:12 280:5,13,17 281:2 281:5,12,13,18 282:1,5,8,10,16 282:22 283:3,8,13 283:15,21 284:1,7 284:9,16,21 285:7 285:19,20 286:2 287:4,4,8 288:12 288:12,18 289:16 290:1,11,19 291:5 291:11,22 292:4 292:17 293:9 294:6,17 295:6,11 295:20 296:10,12 296:18 297:4,13 297:17 299:5,13 299:17 301:14,18	302:11,20 303:1 303:10 304:1,13 304:18,21,22,22 305:3,7,9 306:3,5 306:6,7 307:7,10 307:12 309:20 311:2 312:22 314:16 316:5,6 321:20,20 322:10 325:5,21 326:1,15 330:6 331:7 intakes 46:21 95:4 99:2 112:16 183:14 289:7 293:20 297:6 305:20 325:13 331:15 integrate 137:6 integration 15:7 16:7 137:6 245:9 266:19 integrity 88:10 intended 293:17 310:2 intensity 269:9 271:14 272:22 274:6 intensive 272:18 intentional 332:19 interchangeably 312:5 interest 83:12 92:7 184:12 238:4 239:14 240:2 274:21 interested 11:4 139:11 interesting 96:20 97:2 103:15 113:7 152:2 180:4 182:1 196:9 206:12 213:4 315:6 interestingly 222:2 intermediary 159:14 163:4 164:17 169:19 190:1 208:13,16	210:7 intermediate 156:13 159:18 160:13 161:12 163:13 164:5,9 168:13,20 211:11 211:21 212:3 international 12:10 17:21 internationally 11:12 interpret 320:3 interpreting 66:5 145:13 intervention 84:18 88:19 92:2 107:4 183:3 286:13,17 293:4,13 304:8 interventions 84:17 183:2 interviewing 43:13 intolerance 206:10 intriguing 314:21 intrinsic 93:21 introduction 69:19 invaluable 4:18 9:22 inverse 29:1 30:5 147:3 148:10,17 208:6 252:17,18 271:7 301:2 303:20 inversely 183:5 272:21 296:18 investigate 227:17 investigated 192:9 investigator 52:15 investigators 101:4 283:1 invites 189:7 involve 314:12 involved 16:6 52:22 87:19 169:7 213:18 285:15,16 IOM 20:17 179:11 197:9 232:12 235:20 289:8	290:3 318:2 322:2 Iowa 40:19 iron 305:22 Ironically 234:20 ischemic 180:5 Isles 184:20 isocaloric 39:11 43:17 157:6,9 158:22 159:2 162:3,5 165:20 170:5,13 190:15 214:20 isocalorically 230:11 isoflavone 45:14 isoflavones 45:11 45:16 isolated 72:21 isomers 227:12 issue 29:17 58:4 61:4 62:12 85:9 88:12 96:15 118:4 126:5 127:6 129:15 130:13 152:2 167:2,13 168:11 176:22 184:10,18 191:19 192:4,4 197:22 202:6 203:9 204:4 205:7 210:1 317:19 issues 15:13 44:20 57:1 58:5 122:12 126:19 162:17 202:4,5,19 247:14 277:20 312:21 315:1 320:9 issuing 274:11 Italian 304:7 Italy 197:19 ITEM 3:2 It's 107:1 IV 20:4 i.e 322:14 <hr/> J <hr/> J 1:15
--	---	---	---	--

James 293:7	kept 245:2	114:4,17 115:6,15	135:11 160:3	led 17:15 58:11
January 25:10	key 15:22 45:11	116:1 123:9	201:9 248:19	87:15 270:16
285:2	176:22 199:21	126:10 128:9	254:18 297:15	280:1 285:5
Japan 28:6 34:5	269:4 271:21	142:8 143:7 145:7	304:14	Lee 41:5
Japanese 41:6	273:19 302:20	150:19 151:5,13	larger 11:3 18:1	left 28:10 40:8
178:13	320:15	169:6 170:4,8,18	148:21 182:5	70:21 288:8
Jean 278:11	Keys 216:4	178:7 181:22	211:15 248:15	315:18
jelly 132:7,9	kg 270:19,20	188:14 196:13	294:14	legumes 94:2 97:15
Joan 63:3 136:18	272:11,11	204:11 214:15	largest 139:1	lend 122:14 315:15
Joanne 1:19 22:16	kid 142:10	218:2 220:15	169:16	letters 27:1
22:17 66:21 67:15	kids 67:10,21 68:14	226:19 241:4	Larry 56:13 60:8	let's 33:4 138:9
67:22 85:4 91:16	92:8,8 98:4	260:8,9 263:2	64:9 65:5 116:6	163:6 191:1
92:14 96:16	262:10,15 263:5	278:3 279:1	122:5 124:18	219:17 222:17
117:11 145:16	318:8 321:3,11,13	311:16,22 313:7	127:3 137:18	223:18 228:17
146:3 152:16	323:1	316:12 318:12,12	139:22 144:10	263:12 268:4
173:6 267:12	kind 29:17 37:18	knowledge 6:17	166:20 167:12	276:1 278:6
277:14 318:14	50:21 60:6,19	265:17	187:1 196:8,21	level 65:3 88:8
324:3	70:1 71:18 73:5	knowledgeable	200:14 202:18	103:17 169:3
job 59:15 201:7	75:21 79:22 85:10	186:2	216:18 260:10	179:15 198:5
219:7 238:19	88:22 90:10,22	known 213:14	263:16 265:12	199:17 200:1
266:7 274:21	123:19 124:1	215:11	310:11 311:4	224:7 226:17
311:11	129:2 131:10	Kramer 270:9	316:11 318:14	228:9,13 231:7
Johnson 283:4	133:13 134:19	275:12	Larry's 131:17	235:3 237:14
join 9:11	143:4 144:22		lasted 147:7	244:6 245:3 259:5
joined 127:14	145:1 227:3	L	lastly 22:10 182:9	260:16 308:12
judge 85:10	276:16 313:18,20	L 1:19,20	274:7	326:1
judgment 66:4	315:19 316:8	labeled 281:8	Latino 303:22	levels 46:4,22
juice 115:22 132:16	kinds 66:18 149:17	laboratory 134:22	launch 239:15	156:14 157:3
132:18 146:14	191:22 195:4	lab-based 113:7	LAWRENCE 1:15	163:13,14 166:5
Julia 240:20	196:22 214:12	lack 74:18 79:16	laxation 306:14	186:4,19 194:22
Julie 252:10 261:8	221:6,13 224:9	221:21 242:17	LD 1:14	195:21 221:21
264:16,20	225:7	244:9 312:12	LDL 39:13 44:12	222:15,20 226:9
July 279:16 303:5	Kingdom 31:15	lacking 84:4	155:9 165:11	231:11,17 232:2
June 324:18	35:6	lactating 192:11	169:22 208:7,14	232:20 236:11,19
jury 275:15	know 14:13 25:13	lactation 37:8	216:6	237:11,19 269:22
	37:14,20 48:3,10	194:18 195:20	LDLs 223:4,8	289:12 302:20
K	48:11,17 49:1,15	198:14 269:19,22	lead 153:11 171:3	319:8
K 1:14	50:3,20 52:21	270:2	308:19 326:3	lib 102:2 118:18
Katcher 81:20	55:16,19 58:11	Ladies 4:3	leaders 10:3	132:20
88:16	59:12 60:1 61:8	Lagiou 329:15	leads 64:13	Library 16:22 17:4
Kathryn 2:2 6:6	61:17 63:21 64:10	lamb 53:19	lean 229:13 313:20	117:21
kcal 235:18	67:7 70:6,16	landmark 60:19	learned 260:11	lifespan 19:13
keep 16:16 87:5	76:19 78:1 79:8	language 17:20	262:5	204:14
204:8 213:17	84:20,21 86:12,15	Lanou 298:3	leave 113:20	light 90:13 114:20
275:21	87:22 90:20 91:10	large 23:5 84:12	122:15 124:8	lighting 49:15
keeps 266:17 267:5	92:16 94:18 96:2	87:20 88:3 98:15	218:17 314:13	50:13
Kelly 77:12 234:2	96:7 104:19 113:4	113:10 121:20	Lebanon 11:21	lightning 260:13

261:11	lipids 38:15 39:14	35:12,15,17,22	285:12,13 286:7	315:18 316:1
likelihood 124:9	44:10,13 45:6,8	36:9 38:18 40:21	287:1,15 288:9,11	320:22 333:7
275:8	67:2 79:5 168:22	41:6 43:10 50:16	291:2,3,20 292:14	looked 25:12 30:15
limit 210:5 229:3	169:17 206:9	54:11 75:9,19	296:4 297:9,11,15	36:11 47:18,21
230:21 249:19,22	209:9 211:12,22	80:5 92:2,9 94:8	298:12,21 299:2	56:4 59:16,17,18
limited 16:14 19:3	212:8 223:12	99:20 101:11	299:10,11,12	62:8 64:6 70:9
20:4 38:22 39:18	225:1	106:13,21 109:15	300:2,8,14,22	71:21 77:13 86:21
71:19 75:9 100:3	lipid/lipoprotein	111:7 113:17,19	303:8,18 304:12	95:18 96:17
111:1 121:6 139:5	156:14	117:19 122:6	308:17	107:16,20 109:17
141:1,7,19 149:4	lipoprotein 162:13	130:6,7 133:20,20	long-term 328:16	119:8 143:10
172:10 182:16	163:14 164:11	134:2 138:12	328:20	151:7,16 158:7
232:3 233:7	lipoproteins 169:17	139:7,9 140:10	look 28:14,18 29:13	161:6 164:19
251:10 256:9	206:9 225:2	141:19 183:17	30:2,3,3 31:1	168:11 172:6
280:7 284:12	lipo-proteins	185:15 198:5	33:13 34:9 40:10	212:1 221:9,10
303:15 313:19	211:22	199:16 204:19	41:6 45:4,18	223:6 228:6 234:5
325:19	liquid 24:2 116:11	215:22 218:3,12	49:20 55:13 56:6	234:12 243:21
limiting 37:17	130:14,19 131:6	222:13 223:19	58:20 63:12,17,17	245:2,18 249:5
155:14,20 206:2	131:12 132:4	236:13 238:15	77:2,22 80:6 84:6	250:15 261:14,16
210:4 314:1	133:7,12,14,18	241:3 255:12	93:4,17 97:5	277:10 283:1
limits 74:19 79:17	134:5	263:20 264:8	105:4,20 109:13	298:21 316:21
214:13 229:12	liquids 71:8 130:5	267:21 276:11	110:21 112:21,22	327:1,22 329:2
255:10	130:8,9,12 132:10	283:5,9 295:19	113:1 132:3	332:9
Linda 1:11,14	136:16	314:19 328:11	140:10 141:3	looking 10:3 26:19
13:20,21 25:13	list 18:20 19:6	live 10:20 13:13	144:6,7 147:17	30:1 31:17,20
36:7 51:11 65:15	23:15 85:20	lively 238:17	148:6,11 151:18	32:22 34:10 35:11
87:2 145:6 153:15	329:12	livestock 227:1	152:5 154:14	41:22 49:7 51:7
238:18 274:18	listed 15:15 23:3	living 85:18 114:14	168:8 176:19	77:15 80:10 81:11
322:20	28:9 30:17 173:6	load 305:1	178:13 179:2	82:21 83:13 92:17
line 12:13 29:2	179:21	local 259:6	182:3,10 183:10	104:20 109:3,18
40:22 54:15 89:10	listening 9:13	locations 5:17 11:1	185:9,20 188:12	132:12,15 138:1
89:11 95:8 145:1	listen-only 8:5	183:16	191:3,21 194:4	144:1,5,14,20
216:22 244:19	literally 312:22	logistic 126:19	195:11 198:7,9	149:16 155:22
317:9 323:7	literature 17:16,17	long 23:15 38:18	200:13 209:18	157:5,8 158:14
lined 47:12	19:10,11 21:20	80:15 103:3	210:1,15 213:8	160:4 162:19
lines 30:22 32:3	71:21 72:8 94:9	110:14 116:15	216:11,20 220:8	163:11 172:8
link 32:18 36:1,20	104:22 123:16	121:8 126:16	220:18 221:5	173:17,18 174:4
64:22 107:18	135:22 146:19	129:17 147:6	222:1,8,17 223:3	175:4 180:1,11
120:11 283:15	157:8 158:2,3,7,8	177:14 189:5	223:8,10,10,18,19	186:18 192:10
linked 39:5 41:15	158:21 159:8	194:13 242:18	225:11 233:19	194:1 212:4 222:9
46:8,20 89:4	163:12,20 208:10	278:2 313:17	234:4 240:21	222:20 229:1
99:22 100:13	244:2 251:2	324:13,15 325:14	244:2 247:12	230:20 231:13
140:6 274:6	254:22 258:17	330:5 331:16	256:6 257:5,16	245:17,22 247:8
linolenic 179:8,9	268:17 280:4	longer 181:20	260:21 264:5	247:18 254:18
lipid 78:21 79:1	314:1	210:9 326:17	265:1 266:13	261:2 274:22
163:13 166:5	little 29:7 30:4,9	329:18	276:11 282:15,19	320:1
208:20 209:1	31:6,9 32:9 33:11	longitudinal	286:22 300:1,20	looks 28:12 67:2
220:12 308:2	33:17,21 34:9	280:10,12 281:21	310:2,9 315:1,13	138:21 178:6

loose 124:4	154:2 167:18	318:18 321:19,20	maintaining	191:20 192:7
lose 86:13 123:3,21	170:10 173:7	328:8 329:19	257:22 258:5,9	194:12 268:5,13
124:7 144:18	189:1,3 191:8	330:20	325:7 331:9	268:21 270:3
257:21 324:10	196:11,19 211:15	lowering 45:8	maintenance 117:8	274:4,13
326:11,14	214:17,17,19	lowers 172:12	249:8 257:8	matter 89:3 140:14
losing 258:4,9	218:7 226:20	lowest 297:6	324:11,14,16	153:4 204:2
325:7 331:9	227:1 245:15	low-calorie 326:18	328:8,14 330:6,10	239:12 333:10
loss 36:12,14 45:19	259:4 260:9,9,11	low-income 305:5	332:2	Mattes 132:11
60:2 104:3 117:7	262:15 278:7	low-3 237:18 238:7	major 60:22	maximize 52:1
118:7 121:11,16	312:4 313:4,8	LO3 235:8,8,11,11	129:11,19 294:10	maximum 181:22
131:13,20 134:6	316:1	lumping 151:21	311:1	McGrane 154:2
137:2 249:7 257:5	lots 35:10 62:6	lunch 31:4 102:3	majority 201:12	McMURRY 2:2
257:17 258:1,6,10	115:18 262:5	131:9 132:21	307:16	6:6
268:22 269:7	loud 317:15 322:11	234:21 239:7	making 110:18	McPEAK 2:2
270:3,17,19,20	love 130:4 140:18	luncheon 52:16	198:12 213:12	MD 1:14,15,17,18
271:15,15 272:18	low 93:10 94:17	lung 41:9	262:22	1:20 2:4
273:7,10 274:5,13	96:11 104:3,6	Lyon 168:5 182:15	malaria 18:17	meal 102:5,10
324:11,13,16,22	135:6 149:3	182:20 183:7	Malik 106:21 143:9	119:18 133:8
325:8 326:16,20	174:17 181:7		144:8	134:4 259:12
326:22 327:4	207:20 229:13	M	malnourished	265:20 266:1
328:4,13,20 329:6	233:1 234:11,16	M 1:17	18:15	meals 241:10
330:5,9,19 331:10	234:19 235:5	macadamia 207:5	management 8:15	246:16 256:15,16
331:20 332:1,16	236:5 241:13	208:22	16:1 306:16	mean 48:10 49:22
332:19	243:14 247:6	Macro 259:5	manifestation	53:3,8 87:9 88:13
loss/maintenance	274:7 286:11,12	macronutrient	19:12	89:9 122:8 123:6
328:18	286:12 299:5,17	135:13 289:8	manner 128:14	126:2 150:13
lost 42:11 60:15	302:18 307:4	324:2,6,8 325:2,5	manufacturers	167:12 178:3
82:3,5 88:20	312:14,22 318:9,9	325:9,11 326:16	259:17	188:15,22 189:11
116:22 125:21	320:2,4,7 321:1,5	327:4,19 328:3,13	march 65:21	190:21 196:1,14
142:17 144:21	321:15 322:7,8	329:5 330:12,18	margarine 183:7	214:13 215:2
lot 16:15 28:13	324:11 327:5,6,9	331:5,7,11,13	marine 181:8,13	217:22 226:17
32:3,11 34:6,20	328:5,6,15 329:6	macronutrients	184:12 187:5	264:9 314:10
35:8 36:17 38:4,6	329:7,8 331:3	133:18 135:10	marker 169:10	meaning 169:10
40:6 47:20 53:3	lower 39:5,7 41:15	302:8 330:14	305:17	meaningful 125:7
53:17 56:7 60:1	42:17 45:5 46:8	macro-nutrients	markers 156:15	means 87:12 252:4
62:5 63:12 64:5	46:18 55:7 62:9	51:1	159:14,16,18	252:19
65:8 69:20 70:1,6	74:15,22 75:8	magically 88:14	160:14 161:12	measurable 38:20
70:18 76:22 81:7	80:20 88:1,3 89:4	magnesium 305:22	162:13 163:14	84:16
82:20 83:1,6 85:7	179:13 180:5,14	magnificent 315:4	164:5,9,12,18	measure 13:3
86:22 87:18,21	211:19 223:9	magnitude 19:22	165:12 166:5	41:21 49:21 78:4
89:1 92:7 96:11	230:12 232:21	Mahon 36:11	211:11,21	83:9 89:3 111:2
96:13 97:6,8	242:17 247:3	main 18:20 53:20	markets 243:16	114:20 115:1
105:2 122:12	276:14,20 283:5	179:6 241:1	masked 283:16	138:19 143:22
123:18 124:11	287:18 297:7	maintain 46:21	mass 82:16 297:1,4	194:19 212:3
130:5 131:4 132:3	305:10 306:4,7,9	128:16 162:9	massive 265:9	263:18 264:11,11
133:7,8 135:8,20	307:3,12 315:8,8	324:9 325:13,18	material 317:5	279:21 281:13
137:9 142:9 150:9	315:9,10 318:16	331:15	maternal 154:18	288:3 310:16

311:6 316:5	medical 6:17 9:20	201:3,6,18 202:2	method 97:18	276:5 278:6
measured 35:9	18:11 191:17	202:6 203:9 204:5	methodologically	309:14 312:11
47:19 55:4,5,21	201:16	237:22	256:13 283:18	321:16
76:15 82:12 83:7	medical/scientific	merge 262:7 263:9	284:5 288:8	Mim's 216:19
87:18,21 88:17	220:6	message 91:12,15	294:15	mind 186:1 213:17
271:5 281:7 282:8	meet 229:11 232:11	93:22 94:1 116:5	methodology 255:2	minds 54:6
311:4	255:9 293:20	messages 46:21	271:7,11 314:4	minimal 213:21
measurement	302:19	60:22 61:13	methods 27:16	217:3,6,10
77:10 110:17	meeting 1:8,11	135:15 143:22	55:19 144:2 231:5	minimally 54:7
140:5 310:22	4:15 7:16 8:3,4	messy 105:21	314:13,16	minimum 17:21
measurements	10:16,20 11:6,11	met 17:17 231:15	methyl 193:18,21	minor 213:7
281:16	11:14,16 12:8,16	231:15 271:3	201:17 202:2,6	minus 229:8 304:3
measures 73:13	12:22 13:2,5,10	272:2	204:4 237:22	minutes 13:9
159:19 206:9	13:12,18 14:6,20	meta 58:19 74:5	methyl-mercury	Miriam 1:16
212:2 244:6	15:5,10 20:9	75:15 79:18 99:11	174:17	177:19 240:11
281:12 287:22	48:13 86:11	108:2 138:2 160:3	Mexico 11:20	misleading 90:6
316:2,3 324:20	136:14 312:15	192:13 193:11	MI 183:6 211:17	missed 59:21 61:22
measuring 76:13	meetings 7:20,22	metabolic 157:2	micronutrients	266:14
91:6	10:22 13:1 17:2	163:4 208:5 216:6	237:8	missing 139:9
meat 27:17 28:2,14	70:21 87:3 184:14	221:12	microphone 9:3	141:13
28:14,15 29:5,8	meets 179:10	metabolically	micro-nutrients	mission 146:8
29:14,16 30:19,19	Mellen 77:15	192:17	98:17	mix 179:22
30:19,20 32:2	mellitus 156:13	metabolism 220:13	middle 106:9	mixed 32:8 58:10
33:3,5,9,10 34:12	member 22:10	metabolites 208:13	237:17 240:6	135:15 173:22
34:18 35:11,15,15	members 1:13 4:17	208:17	286:8	180:22 275:6
36:1,19,20,21	4:22 5:15 8:13,19	metal 199:19	Mike 226:21	276:16 296:14,16
37:3 47:17,17	9:11,13 10:9	metals 200:19	milk 26:15,15 37:4	297:19 298:14
48:13,17,22 49:4	13:14 14:1,4 16:5	237:7	56:19 57:1,3	300:5,12,17 301:3
49:8 50:1,5,6,11	16:16 18:22 23:3	metastatic 31:3	102:15 154:19	309:7
52:16,18 53:6	153:18	meta-analyses 26:1	191:4 194:5 195:1	mixing 40:7
55:1,2,4,4,14,15	membrane 180:9	45:2,13 60:10	195:21 196:3	mode 8:5
56:1,2,18,22 57:9	men 29:22 31:4	61:1 74:6 144:17	215:22 242:1	model 151:15
57:20 58:10	34:19	145:3 158:16	270:22 295:10,10	modeling 20:20
167:18 225:4	menasured 305:3	159:21 173:10,12	295:12,12,20,21	89:19 151:14
228:1 235:4 236:5	mental 309:1	173:13 178:20	301:18,18,21,21	152:11 155:11
236:12	mention 21:5 24:10	206:4 211:7	milligrams 155:21	156:1 160:19
meats 31:5 32:17	38:3 71:13 100:8	meta-analysis	172:21 174:11	195:9 200:6,12
33:1,1,1,11 49:9	153:19 168:20	44:19,20 48:12,18	175:17 178:11	205:11 228:17,18
49:10,13 52:17	258:15 261:21	58:16 60:16 80:1	185:11 198:6	229:1,19 230:18
53:10,11,12 55:9	310:14	81:2 100:20,21	230:22 232:3,22	230:19 233:10
64:4 210:14 232:4	mentioned 25:13	105:18 107:20	233:5,18 237:15	237:9 238:14
293:19	36:7 49:11 55:3	119:9 143:11	237:17,19	315:1
mechanism 190:1	56:19 108:14	163:22 165:3	Mim 127:13 203:10	modelings 230:15
213:15	115:13 116:16	176:6 180:17	203:22 214:2	models 158:22
mechanisms	117:4 122:7 216:5	193:8 194:1	217:21 240:13	229:16,18 230:4
149:20 166:3	315:3	206:22 224:10	260:7 262:3	moderate 20:4
media 250:5	mercury 193:19,21	250:15 309:1	263:15 267:11	182:4 212:18

214:9 217:7,12 218:1,16 242:5 251:9 268:21 274:4 290:18 327:9 modest 251:11 modestly 169:13 modifiable 168:18 modified 54:15 235:15 modifier 141:15 modify 123:13 231:9 Molly 154:1 mom 202:17 205:4 moment 153:20 247:14 251:8 255:1,21 257:15 267:8 mons 201:19 205:4 monitoring 12:13 12:21 246:3 264:1 264:3,9 mono 157:21 290:4 306:4 monos 157:13,14 157:20 159:3 323:17 monounsaturated 154:11 156:6 158:7 160:6,9,13 165:19 month 15:10 months 10:4 42:5,5 42:7 117:6,6 131:16,17 197:17 269:13,16 270:15 270:16,17 271:18 272:16 273:7 305:5 326:18 328:17,21 morning 4:4 9:7 14:1 127:15 333:2 333:8 mortality 34:14,19 41:9 173:1 174:6 175:18 176:13	178:10 180:20 182:17 183:15 211:18 212:15 329:10,11,21,21 330:22 331:1 332:4,11,13,17 Motard-Belanger 223:7 mother 196:2 mothers 275:4 mother-infant 192:12 motor 201:1 move 4:20 10:13 23:1 41:12 47:3 69:16 83:16 97:20 122:21 145:14 163:6 166:17 171:6 191:2 219:17 228:16,17 230:17 268:4 323:22 moved 73:6 76:21 moving 245:17 MPH 1:15,17,18,20 2:4 MSEd 2:4 MSW 2:3 MUFA 156:10,19 161:7,11,15,17,19 162:10 163:1 167:1 168:12,12 170:3,9,10 MUFAs 162:19 163:17 165:1,1 166:12 167:14,15 167:17 MUFUs 237:3 multiple 287:22 316:2,3 muted 201:2 myocardial 176:21 MyPyramid 289:10 293:18 <hr/> N <hr/> n 194:9	name 4:10 11:21 173:21 names 13:15 Naomi 1:14 52:9,14 54:4 127:2 226:2 226:9 227:1 266:12 nation 11:12 national 11:18 22:2 259:6 nationally 282:19 nations 150:5 natural 155:8 202:16 279:10 naturally 220:17 227:13 nature 60:19 157:9 277:21 282:14 317:12 necessarily 51:7 54:17 68:12 141:11 318:15,20 necessary 259:7 need 22:8 37:11,14 49:16 72:22 90:14 91:7 92:6 94:17 108:7,9 112:4 115:7 116:3 127:19 128:4,10 137:21 142:10 143:3 145:14 150:9 151:18 163:1 167:4,5,9 170:13 174:20 177:8 181:8 203:12,13,18 213:10 214:21 217:8 226:21 228:16 245:15 256:17 257:21 259:14 263:19 266:18,22 269:11 271:19,20 273:18 295:1 317:13 323:22 needed 20:12,14 45:5 98:18 122:7	175:3 183:13 258:21 259:13,15 259:22 needing 90:18 needs 37:7,16 69:8 112:19 113:15 142:18 162:7 204:8 215:4 255:10 289:14 294:4 311:12 317:2 negate 51:21 negative 29:1 150:19 222:6 237:12 245:14 247:22 251:15 252:3,6,15 253:4 253:14,18 254:8 257:10 258:22 282:2 296:9 297:12 298:15 299:4,14 300:11 300:16 305:15 negatively 325:21 negatives 69:8 neighborhood 244:5 260:16 neither 304:21 NEL 17:1,2,10 20:10,12 21:4 25:9 69:21 71:15 71:19,20 72:4,10 72:17 73:7,9,17 99:6 118:1 119:7 134:20 146:19 151:11 172:3 205:21 243:22 250:16 254:14 268:16 279:14,15 284:3 285:1,10 286:5 287:12 288:7 289:21 290:14 291:1,14 292:9,12 294:13 295:15,19 296:2 297:10 298:10 299:22 300:9,13	301:10,16 303:4 303:16 Nelson 1:16 127:13 128:7,18 177:18 177:21 178:17,22 199:5 203:10 204:7 213:22 214:2,5,8 215:1,9 217:20 218:11 219:5 240:11,14 252:18 253:6,15 260:8,20 262:1,19 263:6,8,21 264:15 266:9,15 267:8,16 275:20 276:6 277:13 278:1 309:14 312:7,11 312:20 313:13 321:16 323:10 net 71:18 115:12 270:2 297:6 Nettleton 77:21 neurological 193:17 194:20 neutral 159:13 161:10 164:2 193:11 212:12 never 5:4 50:4 59:14 new 15:21 24:22 89:15 143:4 154:19 179:13 191:2,5 251:1 254:18 259:3 Newby 305:3 newer 76:18,19 90:1 NHANES 234:13 238:1 315:2 niacin 305:21 nice 22:20 49:6 83:14 87:3 140:7 219:7 309:17 318:1 nicely 47:10 199:1 NICKOLS-RIC... 1:17 92:14 94:5
--	--	--	---	--

112:9,13 114:9 139:3 141:9 142:13 185:5 186:15,22 198:1 199:4,11 204:10 265:11 277:8 nightmare 254:13 NIH 31:18 Niinikoski 286:14 nine 37:5 193:6 287:6 321:7 328:1 329:4 nitrates 53:14 noble 10:1 non 118:4,8 119:1 120:14 121:9 124:20 267:2 297:21 nonfat 320:7 nonfatal 176:21 nonrandomized 81:3,14 non-caloric 23:22 71:6 112:8 115:8 115:11 117:16,17 118:11 119:3 120:5 123:16 124:3 127:8 128:5 129:4,9,18 293:5 non-core 123:10 non-energy 113:14 non-fatal 176:17 non-HDL 155:9 non-NEL 72:7 134:18 135:22 non-nutritive 117:21 118:16,19 119:4 120:12,18 121:1 123:7 125:2 126:7 non-obese 148:5 non-processed 50:6 non-RCT 327:2 non-sucrose 119:14 non-systematic 223:10 Nordic 97:6	normal 39:8,13 42:18 43:4 44:12 103:7 222:17 225:3 228:13 283:11,22 284:2 306:14 308:3 325:22 326:6 normally 223:2 224:8 note 12:19 21:2 26:14,14 67:21 69:18 81:5 106:1 130:6 153:21 188:9 190:20 208:8 262:2,22 263:10 264:17,17 269:6 noted 19:8 notes 12:14 110:1 notice 7:18 58:6 November 13:10 14:21 136:13 146:9 nuanced 151:20 null 147:18,20 number 12:9 19:21 23:5,22 24:2,5,8 24:10 58:8,9 114:5 133:15 147:15 173:10 174:3 201:9 205:14,15 211:15 212:9,21 213:18 227:22 241:7,9 245:18 247:15 249:5 250:15 261:17 262:8 267:15,17,18 283:7 284:4,11 299:20 304:14 306:1 308:16 309:9 325:19 numbers 15:22 numerous 165:12 Nurses 33:7 147:19 Nurse's 33:4 Nurse's 31:19	nursing 194:3 nut 206:16 207:15 207:22 208:11 209:19 210:14 Nutrasweet 125:2 nutrient 16:2 93:4 115:18 155:13,19 156:2 162:6 186:16 203:15 225:6 229:2 230:20 231:14,20 233:20 235:19 237:12 238:2 251:7,20 255:9 277:4,11 289:11 294:2 308:1 322:16 nutrients 46:12 99:2 204:21 209:21 231:13 233:2 293:21 294:12 302:20 nutrient-dense 229:20 251:22 256:20 nutrient-rich 295:2 301:22 305:18 nutrition 4:6 5:19 6:7 16:22 17:3 46:3 100:22 202:17 204:15 252:8 253:9,19 nutritional 14:8 229:11 293:8 nutritionally 230:16 nutritious 294:7 315:16 nutritive 119:2 120:15 121:10 124:21 nuts 155:4 205:17 205:20 206:13,15 206:17,19 207:3,7 208:3,22 209:5,17 210:3,4,11,16 232:16 235:12	236:6,16 nut-to-nut 207:11 n-3 154:14 171:1,6 171:10,17 172:21 173:15 174:16 175:1,6 176:12 177:3,11 179:3,7 181:5,8,8,13,18 182:4,11,17 183:14,18 184:1,5 184:11 186:7,9 187:5,21,21 192:8 193:1,21 194:14 201:1,4,12 202:8 202:15 233:18 234:6,11,11,16,19 236:19 238:10 n-3s 154:16,16 n-6 154:12 162:19 163:6,9 165:5 190:9	objective 7:12 250:9 obliterated 60:21 observation 7:21 196:6 observational 41:18 50:7 105:18 118:7 168:3 181:10 183:11 189:4 212:12 260:14 observed 108:1 obviously 37:12 44:6 46:10 57:21 101:19,21 103:13 104:9 108:5,8 110:12 115:17 118:4 120:6 157:22 158:6 161:2 162:7 169:2 169:3 170:15 174:19 190:1 191:15 192:7,18 194:7 206:13 207:22 208:22 210:4 213:3,10 224:8 225:4,6 229:12 231:3 266:6 314:9 occur 7:22 223:2 occurring 220:17 227:13 ODPHP 2:2,2,3,4 offer 39:1,20 66:11 247:5 offered 248:17 Office 6:2,5,7 officer 5:21 official 10:5 officiating 4:12 offspring 275:2 off-base 310:16 oh 86:17 145:19 226:16 Ohlin 273:17 oil 167:16,16 180:4 209:22
--	--	--	---	--

oils 207:18 230:11 232:5,16	240:4 308:6 Opening 3:3	164:17 279:22 315:20 324:19	310:5 324:5 325:1 331:6	103:18 109:14 110:6 165:19
okay 42:11 47:5 51:9 56:9 59:2 94:5 108:13 112:12 115:10 122:21 134:8 138:10 166:17 170:1 171:1,6 178:17 179:1 186:15 190:11,19 191:1 199:4 210:18 215:5 219:16 227:8 233:9 238:15 253:18 267:9 268:4 274:15 275:17 276:1,4,6 277:13 278:4,5 308:4 311:14 312:20 323:20 332:20	opens 148:20 open-ended 21:19 operates 7:8 operationalized 229:7 operations 9:2 opinion 20:5 opportunities 8:6 205:11 opportunity 14:15 opposed 29:22 111:4 175:5 203:19 276:17 310:19 311:19 321:19 opposite 97:1 optimal 46:3 295:2 324:8 325:16 326:10 327:16 options 247:3 order 1:11 10:5 13:3 293:19 302:19 308:1 ordinarily 218:9 Organization 269:17 organizational 10:10 organizations 22:3 original 25:22 74:5 98:3 99:10 101:1 107:2 192:19 221:14 244:1 312:3 originally 73:19 ought 111:5 ounce 236:11,17 ounces 172:20 194:16 234:6,10 234:15,18 235:2,5 235:7,10 outcome 20:1 101:1 119:10,12 146:11 147:18,21 147:22 159:10	outcomes 23:11,14 23:19 25:11 38:21 71:2 84:17 147:17 150:1 151:8 154:10 155:3 156:14 159:4 160:7 164:6 165:7 168:13,21 169:2 191:5 193:15 194:19 195:19 196:1 198:17 199:22 201:2 206:7 208:4 210:10 211:13 221:11,18 223:3 224:22 258:2,4,8 258:12 259:3,7 286:20 331:21 332:3 outliers 228:10 outpatient 109:15 output 270:22 outside 8:21 135:3 149:5 223:16 325:12 331:14 overall 21:11 26:21 30:4 31:5,10 38:17 40:21 41:11 45:4 49:13 64:7 69:3 74:11 81:9 82:5 90:13 93:17 93:20 97:10 100:10,15 105:4 108:2 110:2,11 111:16 114:6 118:18 133:10 140:2 142:15,16 148:14 155:13,19 172:8 176:16,20 180:17 181:1 182:21 201:6 229:2 236:17 237:8,13 241:4 284:7 285:11 292:14 298:4	overarching 278:13 overconsuming 320:16 overlap 64:5 80:7 82:20 83:6 121:13 130:5 137:10 277:5 overlaps 24:11 overnight 204:18 overseas 258:16 overshadowed 10:8 oversight 15:18 overt 222:8 overview 315:4 overweight 99:8 118:13 121:4 246:13,20 249:15 251:12,17 252:5 256:12 281:18 282:12 283:20 286:11 293:11 303:22 304:7 314:15 324:10,20 326:8,12 overweight/obese 326:13 over-consumption 289:1 over-processed 87:14	parent 320:3 parents 321:7 Parma 197:19 part 7:19 45:17 62:1 71:16 91:15 93:3 108:11 131:22 139:13 141:1 145:18 151:15 161:5 164:12 171:22 172:5 173:14 174:8 175:8 177:8 180:3 182:14 206:12 238:1 266:10 287:17 307:11 317:3 participants 8:5 12:2,10,14 14:3 26:6 74:8 112:17 119:17 181:11 participate 8:6 11:1 participating 5:16 11:13 271:1 participation 11:20 participations 184:4 particular 113:6 155:2 168:9 176:15 191:19 197:1,3,11,22 204:2 208:5 221:17 237:21 240:11 333:3 particularly 13:15 141:3 154:15 156:8,17 157:19 158:2,14 159:15 160:2,18 163:11 164:11 167:9 170:19 194:14,14 206:17 207:10 208:11,16,19 209:8 211:14,16 211:18,21 213:12
Oken 200:21 old 216:9 293:1 older 99:8 324:19 331:20,22 332:9 332:12,16 olds 278:21 olive 167:16 omega 189:19,19 Omni 58:11 59:8 60:18 61:18 once 117:13 315:17 317:19 ones 58:15 71:14 143:7 165:19 203:20 240:16 287:16,16,19 one-day 102:5 one-fourth 289:6 one-year 293:7 onions 136:8 online 8:8 13:4 onsite 5:17 open 7:12,19,20 57:13 65:18 74:2 184:8 238:14			<hr/> P <hr/> package 186:10 PAGE 3:2 pairs 192:12 palatable 289:2 palette 125:1,3 129:15 Palmer 108:20 panel 152:16 paper 147:11 306:11 papers 146:6 213:2 parallel 101:14	

215:20 217:15 228:19 233:3 310:17 324:4 326:4 parties 11:4 partners 5:12 passive 288:22 path 112:8 127:8 pathway 164:12 patience 239:6 333:6 patients 18:14 158:19 201:18,21 231:2 329:17 Patricia 154:1 pattern 20:19 46:17 155:11 228:18 236:4 307:11 patterns 63:19 150:6 156:3 158:13 229:10,17 229:20 230:4 231:7,12,19,19,22 233:21 234:5 235:1,14,17,18,20 236:1 237:10,13 238:6 279:1 315:2 315:15,17,19 325:11 331:13 peanut 207:17,18 peanuts 206:19 207:16 209:4,16 209:20 Pearson 1:17 153:11,14 167:8 168:2 169:1 170:14 171:6 184:7 189:21 190:11,19 191:1 195:7,15 197:12 200:3 203:4 205:8 214:1,4,7,19 215:6,15 217:14 218:7,13,20 219:15 225:17,22 227:9 228:15	233:13 238:13 pediatric 67:4 Pediatrics 250:4 269:18 peer 18:19 260:3 Penelope 2:3 6:1 Penny 9:4,7 10:18 people 18:12 43:4 43:12 49:21 52:15 55:4,20 62:4,11 69:9 70:6 76:18 78:14,17 79:8 82:3,10 83:13 85:18 86:5,13,21 87:15 88:13,18 89:5 90:3,7,12,14 90:16 91:5 94:21 95:17 105:8 106:7 108:4 111:5 112:4 114:15 115:3 116:20 117:10 120:17,21 121:4 122:20 123:1 124:12 125:1 127:10 128:9,11 128:12 133:8,13 133:16 134:3,14 134:15,15 139:13 140:12 143:16 167:14 170:8 173:11 178:13 181:17,19 189:6 217:12 218:4 220:14 228:1 234:3,3,14 237:18 247:2 250:9 257:17 260:18 276:18 312:4 319:13 peoples 239:1 percent 18:2 76:3 76:17 78:7 82:12 83:20 94:10,13 95:14 103:8 104:4 104:5 113:4 131:20 155:15,16 157:1,2 160:11,20	161:1,2 164:4 179:10 216:2 224:4,6,7 227:21 228:6,12 229:4,5 229:9 230:5,6,13 230:14 241:8,10 241:11 275:6 282:21 283:4 289:4,14,15 293:11 294:4,5 297:3 304:3 305:1 316:6,15,18,22 317:9 318:4 319:8 322:7 324:21 326:2 330:8 percentage 57:20 70:4 241:10 283:2 Perez-Escamilla 1:18 62:21 63:3 136:18,19,21 137:16 149:1,2 215:10 216:16 268:7,9 274:19 275:5 308:8 perfect 101:13 110:10 period 80:16 147:8 158:18 164:1 184:17 206:5 211:6 313:17 329:18 periods 192:15 210:7 person 93:8 123:6 123:8 248:17 personally 8:16 115:16 persons 158:19 173:2 326:13 327:18,21 perspective 105:18 151:17 265:7 pertinent 18:9 Peru 11:21 pharma 197:18 PhD 1:14,14,15,16 1:17,17,18,19 2:1	2:4 phrase 128:14 145:9 phrased 64:12 117:1 141:14,14 312:3 phrasing 65:4 140:22 141:18 physical 20:17 258:8 269:22 304:13 310:16,22 physicians 201:21 Physician's 33:17 physiological 72:22 pick 51:14 124:14 134:13 333:1 picked 67:9,11 166:7 178:19 picking 333:4 picture 63:17 166:21 piece 123:12 146:9 267:4 308:6 316:13 pieces 92:22 93:5 199:13 228:17 pile 262:4 pistachio 207:6 pistachios 209:1,6 Pi-Sunyer 1:18 170:2 195:16 227:20 239:17,20 252:22 253:11 260:6 263:14 267:10 268:4 274:15 275:18 276:1 278:5 308:4 309:11 313:11,15 319:1,16 321:22 323:14,20 place 128:18 131:22 257:16 placebo 297:2,8 places 29:19 109:18 167:19 202:9 241:6,7,16 262:15	placing 6:17,20 plan 17:15 planning 203:1,1 plant 37:13 42:9 46:6,11,15,19 69:5,5 171:2,17 179:6 181:6,8,20 182:17 183:14 184:1 209:21 213:6 plant-derived 154:16 179:3,7 182:11 183:18 plasma 155:9 183:5 plausibility 281:11 283:13 plausible 281:4 282:5,16 play 133:22 136:3 plays 295:21 301:19 306:12 PLCO 31:18 please 12:18 22:11 152:21 171:7 172:16 222:18 235:15 239:9 324:16 330:3 331:17 pleasure 153:15 plus 29:1 107:3 237:15 248:5 point 48:7 52:2,10 56:4 60:9 77:8 87:2 90:20 92:21 114:11 116:12 120:2 143:19 151:8 152:5 166:18 167:2,13 169:4,9 178:21 179:9,10 181:14 184:8 186:7 190:6 195:8 204:22 214:22 215:7 228:9 232:18 239:1 247:12 256:3 273:14 275:16 310:1
--	---	---	--	--

311:4 316:1,20 317:18 318:15 322:6 pointed 120:2 137:14 187:8 pointing 48:15 55:12 points 12:2 48:19 109:11 117:10 143:20 150:14 policies 184:15 policy 4:6 7:5 10:6 14:19 243:11 pollutants 174:18 poly 157:21 polyphenolic 213:1 213:14 219:12 polyphenols 213:7 polys 157:13,20 323:17 polyunsaturated 154:12,14 163:7,9 165:5,21 290:4 poor 244:7 271:10 288:3 pop 132:8 population 18:17 88:8 113:11,22 114:14 121:2 129:12 156:16,21 157:1 158:10 168:1 169:12 175:2 184:20 192:10 211:8 217:19 224:4 227:21 228:11,12 233:8 235:9 262:9 285:21 287:6 288:14 291:7 292:18 305:7 populations 18:3,7 18:8,15 181:16 182:3 206:1 pork 53:6,19 portion 114:22 240:1 245:22 247:6 248:11,15	248:19 259:17 265:3 portions 247:4 249:1,2 positive 27:21 28:22 29:9 31:4 34:13 35:14 47:20 49:4 64:17 81:12 91:8 93:22 98:19 107:5 119:21 120:11 147:22 150:17 159:12,17 161:9 164:2 169:20 193:12 201:5 212:10,13 222:4 245:14 248:7,9,14 250:17 251:15 252:4,9,10 252:12,12,19 253:1 255:14,16 256:1,4 257:13 258:12,21 279:10 280:4,12,21 281:1 281:3,10,22 284:8 285:19 286:20 287:3,17,21 288:11 289:22 291:4,10,15,21 292:3,15 294:16 294:21 295:5 297:16 298:14 299:2,3 300:18 301:3 302:14 positively 292:5 positives 30:21 33:2,6,13 69:7 193:10 possibility 107:13 129:2 207:10 possible 22:9 37:13 73:21 74:2 80:8 89:16 123:22 247:11 312:18 possibly 27:15 313:20 Post 2:4 4:3,10 9:11 10:17 190:7	190:7,12,22 posted 13:7 postpartum 268:6 268:21 269:14 270:3,17 271:9,15 271:18 272:8,13 272:20 273:4,8,10 273:14 274:4 post-menopausal 32:5 41:4 potassium 16:3 potatoes 147:9,14 148:1,3 150:17,19 151:1,7,13 potential 19:11 42:13 70:9 119:5 196:17 201:10 213:9 262:17 potentially 49:14 60:15 69:5 70:5 107:17 110:15 188:1 196:18 poultry 28:15 30:1 30:4,20 33:2,14 33:16 34:15 35:16 37:3 52:19 57:6 57:21 232:5 235:4 236:5,14 pounds 125:21 265:21 power 269:5 powered 273:20 practices 260:1,2 pre 41:4 prebiotics 24:9 71:12 135:18 136:6,8 precedes 141:15 precise 314:13 precision 66:8 prediction 144:13 predictor 83:4 predominantly 142:1 predominates 96:3 preferable 202:8 preference 17:22	18:2 preferences 265:16 preferred 46:16 pregnancy 37:8 194:17 195:19 198:13 pregnancy/lactat... 204:13 pregnant 192:10 201:12 preload 102:9 131:8 132:20 preloads 131:3,5 premenopausal 32:5 premier 42:4 109:6 116:8 131:15 132:4 preparation 27:16 prepare 16:4 243:18 248:22 prepared 204:17 preparing 6:22 15:4 preponderance 6:16 9:19 280:2 301:6,12 preschool 278:22 305:6 presence 242:15 present 1:13,22 15:11 21:13 25:11 52:4 61:9 70:22 99:7 130:18 138:20 140:1 148:18 152:12 246:4 273:12 277:12 303:12 307:8,16 presentation 63:4 66:22 239:21 269:10 308:11 presentations 8:20 16:17 19:9 presented 16:13 21:17 22:7 24:15 24:17 70:20 83:2	86:11 136:15 146:9 197:9 215:17 251:6 264:21 309:2 321:18 presenter 267:20 presenting 47:10 146:4 155:18 267:20 presents 117:6 191:7 preserved 54:1 presiding 1:12 pressure 27:9 34:22 35:3 38:13 38:15 39:5,8,9 41:13,15 42:2,14 42:16,18,19 43:4 43:5 46:8 47:21 58:5,22 59:7,11 59:19 60:4 67:1 74:15 75:8 152:10 156:15 163:15 168:21 173:20 212:5,8 presume 150:4 pretty 45:15,17 57:21 66:12 78:6 84:11 87:22 88:1 89:2 96:14 103:17 104:22 105:6 106:16 111:6 114:3,7,21 115:5 138:21,22 139:5 140:11 196:12 261:12 265:22 311:10 319:11 327:13 prevalence 278:17 prevent 121:11 274:22 284:14 preventing 5:8 prevention 6:3,5,8 9:8 173:18 175:12 183:12 187:9 previous 141:22 154:7 172:1 173:2
---	--	--	---	---

177:16 211:15 279:17 290:15 318:13 previously 141:2 215:17 228:21 pre-menopausal 27:13 pre-pregnancy 272:5,16 price 267:1 primarily 198:9 267:17 290:4 300:5,6,10 primary 6:17,20 45:17 117:3 173:17 174:3 291:13 298:9 principal 293:16 prior 179:11 282:4 private 243:12 probably 36:16 48:8 49:11 50:2 52:4 57:20,21 59:14,22 65:1 67:6 69:2,8,16 75:19 78:4 90:6 91:7 96:9 105:12 110:19 116:15 123:21,22 127:22 135:10,15 142:10 148:18 151:13 168:17 202:21 260:18 277:6 312:5 probiotic 136:10 probiotics 24:9 71:12 135:19 136:6 problem 28:11 108:12 126:16 127:22 139:13 141:1,17 145:9 189:1 322:4 problematic 145:14 problems 5:7 226:3 proceed 152:22	153:9 proceeding 13:17 153:4 proceedings 239:12 272:19 333:10 proceeds 12:16 process 4:21 5:14 7:19 8:7 10:12 17:7,14 20:11 21:6 25:14 52:11 146:19 196:10 221:4 287:12 292:10 processed 27:16 28:2,15 29:16 30:19 32:10,17 33:1,10,11 34:12 36:20 47:17,17 48:10,13,17 49:3 49:8,9,13 50:1,5 50:11 52:17 53:7 53:10,12,14,21,22 54:7,9,12,14 55:1 55:14,18 56:1,2 64:4 85:8,12 219:14 241:21 243:20 320:11 processing 48:22 produce 243:16 produced 220:11 product 76:4 91:4 productive 10:15 14:6 products 23:11 26:11,15,20 27:7 27:19 28:1 30:11 31:8,10 32:14,17 33:19 34:1 35:3 35:21 37:11,14 56:17,22 57:10 64:19 90:6 96:13 147:12,21 152:7 215:13 220:22 221:1,2 223:1 225:3,4 227:4 235:13 236:6 295:11,12,21	301:19,21 302:18 Professionals 33:8 profiles 78:21 79:1 213:14 308:2 program 293:8 305:7 programs 104:3 progressive 263:3 Project 200:21 promote 93:22 279:7 290:5 306:18 308:1 315:20 promotes 120:15 promoting 307:1 promotion 4:7 6:3 6:6,8 9:9 promptly 7:13 proper 317:14 proportion 234:14 250:10 324:2,7,9 325:3,6,17 326:10 327:4,16,20 328:4 328:13 329:5 330:19 331:5,8 proportions 235:18 325:10,12 326:16 331:12,14 propose 16:11 21:14 204:20 250:2,12 proposed 15:1 21:16 126:22 242:4 246:7,9 247:1 248:13,21 249:17 251:19 255:7 266:16,20 268:19 280:1 285:6 288:16 290:17 295:4,18 303:7 317:20 325:4 332:11 prospective 19:5 25:12 28:4 30:10 30:13 31:14,19 32:15,21 33:21 34:4 35:3,5 36:4	40:2 41:18 42:21 43:7 64:21 75:8 75:15 77:17 79:13 79:20 80:9,21 92:3 94:3 98:18 107:3 108:20 114:19 119:20 139:18 141:4 142:3 144:19 145:3 147:6 158:16 163:21 173:9 176:6 179:18 180:12 181:10 184:3 193:7 206:4 207:19 247:10,20 248:5 250:20 257:10 261:7 269:2 271:3 272:1 272:20 275:14 313:9 328:2 329:3 prospectively 143:17,20 prospectives 36:17 prostate 26:11 30:8 30:11,16 41:9 protect 279:7 303:13 315:20 protected 84:11 protection 39:2,20 166:4 190:5 protective 42:8 77:7,16,18,20 78:8 80:2,8,11 93:11,18 95:6 96:7 100:16 105:6 114:8 176:11 182:22 183:20 216:6 254:2 296:9 296:19 297:12 298:6,16 299:14 300:6,12,17 301:2 301:8,13 302:11 303:20 305:15 307:9 protects 72:18 74:13 75:6	protein 3:4 16:2 22:15,19 23:7,9 23:11,13,13 24:6 24:19,22 25:3,4,5 26:10,20 27:6,11 27:19 28:1 30:10 31:7,10,11 32:14 32:16 33:19,22 35:2,20 36:13 37:7,12,13,16,17 37:19,21 38:1,2,5 38:10,10,12,14,19 38:20 39:1,4,7,9 39:12,20 40:10,11 40:11,14,15,18 41:3,13,14,21 42:8,14,16,17 43:14,16 44:7,8 44:11 45:5,7 46:3 46:4,5,7,12,13,14 46:21 47:3 48:8 48:20 51:20,22 56:17,21 57:5,9 57:14,15 58:6,10 58:11,14,22 59:6 59:7,9,10,11,18 60:2,5 61:11,15 61:19 62:4,10,12 62:14,14,18 63:6 67:1 69:6,10,19 69:20,22 70:1,3,3 70:5,7,8,10,12 71:10 115:2 135:15 186:10 209:21 221:21 232:9 237:1 289:4 302:10 306:6 324:14 325:18 326:11 327:8,9,17 328:7,8 329:19 330:4,7,21 331:3 proteins 25:8 37:2 37:6,9 39:10 43:17 59:16,17 70:17 135:13 159:16 prove 124:10
--	---	--	---	--

proven 72:22	pull 137:21 220:20	207:22	281:14	quoted 331:2
provide 7:11 19:15 37:4 129:4 183:20 200:2 224:21 284:17 290:5 330:8	pulled 143:3	quantitate 319:13	questionnaires 53:17 311:7,11 314:12	quotes 265:18 266:11
provided 10:10 12:10 118:1 119:18 284:7	pulling 138:6	quantity 208:1	questions 15:3,7 16:12 17:9,15 18:6 20:9,11,19 21:14,19 23:5,7,8 23:9,16 24:14,16 24:20,22 26:17 29:15 33:15 37:20 37:21 38:8 47:2,5 53:7 54:21 56:14 66:22 69:22 70:12 71:21 73:8 75:1 79:9,9 95:8 98:2 112:6,11 113:18 117:14 120:9 122:2 128:4 134:9 135:20 136:11,15 137:7 146:6 156:8 171:8 172:7 184:8 191:16 195:15 204:6 228:18,21 238:12,14 240:4,5 240:7,15 244:22 247:16 257:3 260:7 263:12,15 267:11 274:16 275:19 276:2 278:7,9,12,14 279:4 310:12 312:12 316:10 324:7 325:15 331:17,19	quoting 265:18 266:11
provides 14:14 15:18 116:10 172:20 175:16 200:12 256:20 295:19 301:17 315:12	pun 310:2	question 18:9 21:1 25:2 26:9 36:3 38:9 45:14 53:5,8 54:5 57:18 61:15 62:3,18 63:4 67:6 71:6 73:15,17 82:22 85:3 92:15 93:12,20 98:3,4 98:10 100:17 102:20 105:8,15 108:16 112:7 114:12 116:10 121:7 128:6 129:8 130:10 135:18 138:15 139:12 140:13 141:13 146:12 154:7 155:7 156:1,9 158:5 161:5 162:20 163:7 166:20 168:9,12 168:12 171:15 172:14 175:8 177:8,22 181:21 184:17 185:6,14 187:2,4,4 189:16 191:6 195:9 197:11 198:2 200:15 205:18 210:20 214:3 220:1,5,9 228:5 240:11,12 243:11 251:7 267:13,22 268:11,14,18 278:13,16 279:11 279:15 290:11 295:9 303:3 308:11,13 309:6 309:18 310:13 311:16 324:5 325:1,16 331:21 332:5	quote 265:19,22	
providing 8:7 11:5 191:18 294:11 302:2,4	purchase 56:1 243:17			<hr/> R <hr/>
proxy 264:12	purchasing 56:1			Raben 103:5
PT 2:3	purist 168:17			RADM 2:3
pubertal 286:18	purpose 18:14			Rafael 1:18 63:2 136:19 149:2 192:6 200:5 202:3 215:11 268:7 274:16,16,17 275:19,21 276:2,3 276:4 278:6 308:9 309:6
puberty 305:2	purview 7:7			Rafael's 238:3 309:22
public 5:7 7:13,16 7:18,21 8:2,4,6,8 8:19 9:13 10:1 12:2,14,22 13:13 13:17 14:2,10 15:10,13 16:21 21:5,18 22:12 25:3 70:6,21 123:19 135:20 136:7,13 191:15	put 51:17 53:16 54:10 78:14 80:2 91:3 101:6 105:21 122:21 132:17 150:20 170:15 178:1,8 183:6 195:18,19 218:14 240:22 311:18 315:2 317:22 319:18 323:18 330:1			raging 169:11
publicly 24:17	puts 251:16 252:5			raise 152:2 317:18 325:14 331:16
published 6:19 72:11,13 73:18 80:21 84:15 85:6 88:16 109:17 132:12 193:4 265:14 268:18 272:3 280:9 282:3	putting 28:8 47:8 127:16 170:16 319:2 322:1			raises 60:9 202:20 231:22
PUFA 164:3 165:10 166:1 167:2 190:9,17	puzzle 316:13 317:3			raising 155:14 230:7
PUFAs 162:19 165:1 166:12 237:4	Pyramid 306:2			Raj 4:5
	P-R-O-C-E-E-D-... 4:1			ran 134:19
	p.m 239:11,13 333:9			randomized 19:4 36:6 42:20 43:19 43:20 44:16 45:18 62:3,15 66:14 73:1 74:19 75:16 78:10,12,19 79:16 79:21 80:5,13 81:4 82:3 84:14 102:1 119:16 121:8,21 122:7,10 158:14 159:12 161:8 163:12,20 164:8 166:8 167:10 173:9,16 175:3 177:13 181:9 183:13 184:2 206:3,20,21 207:5,6 208:21 211:7 212:6 217:16 218:8 269:1 270:10,13
	<hr/> Q <hr/>			
	quadrupled 278:20			
	qualifying 66:9			
	qualitative 277:21			
	qualities 157:6			
	quality 19:20 60:13 62:10,12 69:10 151:9 161:9 170:19 212:13 259:18 270:7 277:16 278:3 280:21 294:15 302:9			
	quantification			
		questioning 88:10		
		questionnaire 53:4		

275:10 286:1,6 291:8 292:13,20 296:5,7,8 300:1,3 303:19 308:17 327:12 328:10 randomizing 189:6 randomly 121:2 range 46:15 147:16 149:8 157:18 161:3 174:9 178:11 181:11 184:4 185:18 186:21 209:19 215:19 218:18 273:16 289:8 319:3,20 321:19 322:2 ranges 230:16 290:3 330:14 rapid 273:7 Rastogi 180:3 rate 180:19 215:14 216:6 274:7 306:20 313:22 rates 18:1,3 244:17 253:10 261:18 ratings 280:22 ratio 200:11 235:8 324:21 rationales 7:2 RCT 193:8,11 223:7 247:12 252:7 258:14 291:3 292:2 RCTs 75:9 80:20 100:4 192:13 193:22 222:4 249:5 258:13 288:9 298:11 313:9,12 327:2 328:1 329:3,13 330:16,17 RD 1:14,17,19 2:1 RDA 70:3 232:17 235:21 RDAs 235:20 reach 11:3,19	188:19 reached 63:7 137:3 reaching 272:15 read 68:20 85:14 90:10 187:2 318:7 reading 145:7 175:21 317:21 ready 21:12 97:20 239:7 243:7 ready-to-eat 80:10 real 33:9,16 34:17 35:18 41:11 56:5 128:19 129:7 254:13 realize 222:14 really 25:1 26:2 28:7 50:11 55:21 56:21 57:5,10 61:13 62:7,15,17 62:19 71:17 77:10 84:4 85:1 90:8 91:8 94:4,17 95:20 96:11 97:11 97:18 102:20 104:4 105:3,21 107:17 111:3 116:3,13 117:3 118:1 121:11,17 121:22 122:11 123:18 124:10 126:2,17,21 127:9 127:16 128:4 131:21 132:1,18 134:10,10 135:19 140:3,14,16 143:14,21,22 144:16 145:13 153:20,22 158:11 158:17 161:6 162:3,20 166:10 167:19,20 168:7 169:17,18 182:6 184:18 187:11,15 187:18 188:11 196:9,20 197:16 198:17,18 199:16 200:15,20 202:12	213:6,7 216:4 218:15 222:7 224:5 228:4 238:21 239:4 241:12,22 247:13 255:19 260:22 261:8,9,9 262:5 263:4 264:10 309:17 310:16,18 311:12 314:10 317:2,12,15 321:10 322:6,10 322:17 reanalysis 83:20 reanalyzed 76:5 Rear 6:1 9:6 reason 58:17 72:8 255:4 270:1 277:1 312:1 320:20 reasonable 7:14 208:10 reasons 51:12 71:16 134:8 168:7 recall 68:19,21 91:18 94:9,12 226:21 318:4 receive 13:2 received 21:6 191:14,15 197:6 receiving 10:3 receptors 31:22 recognize 5:9 51:18 186:8 recognizing 199:15 recommend 89:22 202:12 226:9 274:10 recommendation 69:3 90:13 97:11 97:14 127:4 177:15 184:16 185:10 199:21 231:4 269:14 recommendations 5:3 6:21 7:1,5 14:17 15:8 19:15 20:21 22:2,5	46:18 64:15 68:14 69:4,13 90:8 92:7 130:3 136:5 152:13 167:3 170:22 179:11 183:9 185:4 190:15 192:2 210:2 225:9 231:1 232:12 258:20 318:3 recommended 46:4 46:22 99:1 184:19 232:19 289:12 293:20 302:18,19 307:17 319:20 322:16 recommending 200:1 reconsider 65:16 140:19 record 153:5,5 239:13 recording 11:5 recordings 11:7 recordkeeping 7:15 records 281:15 rectal 29:11 recurrence 183:6 recurring 145:8 red 28:2,14 29:8 30:19 33:1,5 34:11 35:15 36:20 53:6 55:15 80:3 167:18 redo 72:14 reduce 116:20 120:8 180:19 182:17 230:9 231:10 259:17 284:15 reduced 74:17 79:15 98:21 129:1 166:1 172:22 173:20 175:17 208:3 212:15 230:14 232:2,14	253:10,12 307:13 326:14 327:18,21 reduces 17:7 reducing 5:6 127:11 183:15 232:4 322:11 reduction 119:10 119:12 123:9 131:12,14 176:13 268:6 276:12 reductions 158:1 232:9 233:2 refer 8:14 17:2 64:1 reference 11:7 203:9 235:3 325:13 331:15 referred 17:1 37:6 194:17 refined 81:22 82:4 84:18 86:1 88:17 89:5,20 241:20 318:11 reflect 9:19 54:17 204:19 regain 327:18,21 regard 51:20 60:9 170:3 326:22 329:14 regarding 8:21 18:22 63:5 275:16 regardless 302:15 307:19 region 184:22 Register 7:18 registered 11:11,15 12:8 registrants 11:17 regular 101:16 102:3,12 109:21 regulating 295:22 301:20 302:16 307:20 regulation 90:18 91:2 Reid 101:14 109:21 110:4
--	--	---	--	---

reinforce 205:7	252:3,20 254:8	230:10 295:1	257:2 289:11	328:7
related 15:18 18:13	255:14,16,18	replacement 160:5	293:22 294:2	results 21:12 32:18
24:1 27:12 57:1	256:1,4,5,8 257:7	160:10,12 161:1	research 5:11 15:3	39:14 44:13 51:6
58:5 61:4 67:3	257:11 261:4,12	161:11 164:3	16:12 17:14 21:13	63:11,11,14 64:3
71:7 105:16	261:15 268:12	165:21 166:1	22:5 35:22 63:8	66:5 77:13 133:1
117:18 125:9	271:13 276:14,19	190:16	69:2,13 92:6,9	135:2 148:2 150:4
138:15 160:7	308:13 309:3	replacing 120:7	98:18 127:17	161:20 168:15
165:7 199:18,19	324:6 325:2 327:3	156:18 161:6,20	128:1 129:8 130:3	236:21 279:9
204:6 205:19	328:3,11,12 329:5	163:1 165:8	136:4 140:3 150:9	283:17 296:15,17
207:15 208:3	330:18 331:4	170:20	150:10 162:17	298:13 300:18
210:21 242:21	relationships 30:5	report 7:1 10:4,14	166:16 167:3,4	301:3 308:22
245:19 260:16	30:6 105:14 149:9	14:16 15:5,12,21	171:8 174:15	retailers 259:17
261:18 277:20	242:22	16:8,19 20:16,18	175:2 182:2 183:9	retention 268:6
282:16 308:11	relative 146:10	52:12 63:8 115:4	197:7 213:12	272:7,11,12
314:2,5 325:6	192:2 193:20	122:16 153:1,16	225:10 258:20,21	retract 123:12
331:8	194:9,9 215:17	155:10 179:12	259:5,5,11,15,21	retrospective 275:9
relates 14:11 67:19	220:12 223:13	197:10 235:21	270:7 279:4	return 152:21
279:11	225:12,13 226:8	238:3 265:6,13,18	299:16 315:18	153:5 239:8 272:5
relating 9:20 163:2	259:8	266:5 268:15	325:1 331:21	returned 239:13
170:4	relatively 88:7,9	288:5 318:2	resistance 159:20	review 6:18 12:1
relation 92:16	183:17 186:3	323:11 332:6	164:18	15:17,19 17:5,10
113:15	215:22 273:21	333:4,5	resistant 160:17	17:12,14,17 19:10
relations 34:13	274:5 288:3	reported 27:22	resolve 121:9	20:10,12 21:4
relationship 23:10	relevance 14:9	115:5 164:21	129:22	25:6,9 28:3,11
23:12 26:10 27:14	relevant 7:12 12:3	272:19 297:16	respect 52:12	40:1 43:19,22
29:18,21 32:1	18:16 51:13	329:18	respond 12:19	44:18 46:6 62:6
33:5,16,22 34:17	113:12 160:18	reports 20:17 66:3	response 70:14	70:9 71:15,19,22
35:18 37:22 38:11	rely 238:3	197:10 239:16	152:5 160:16	72:7,10 73:8,9
38:13 40:18 41:2	remain 120:10	257:19 280:16	178:2 185:17	75:13 76:1 77:12
41:12 42:13 49:18	remaining 15:3,12	281:5 282:5,16	210:17	79:18,19 80:1,4
55:10 71:1 73:9	24:16 273:1	284:7 285:14,15	responsibilities 7:4	81:2,3 84:10
102:6 103:21	289:13 294:3	285:16,18,22	rest 52:3 313:10	94:21 99:4,5,6
104:7 108:17	remark 54:13	represent 279:5	314:8 320:9	100:12,20 104:22
109:1,8,12,20	196:21	representative	323:11 333:3	117:21 118:2
110:3 112:18	remarks 3:3	282:20	restaurant 247:4	130:17 131:1
116:18 117:5	202:14	represented 207:7	248:8 259:16	134:18 135:22
119:22 142:4	remember 22:11	representing 4:12	restaurants 241:9	139:1 146:15,19
146:13 148:10	43:11 85:14 98:3	represents 95:14	242:20 244:15	158:20 172:2,3
155:3 171:9,16	104:8 114:6	reproach 169:18	246:18,22 261:17	173:5 176:4,20
172:15 175:9	remind 8:11 21:18	reproducible 17:6	262:8,12,13	179:19 193:5
179:2 182:10	22:6	request 190:8	321:14 323:8	206:20 207:4
208:6 212:13	reminded 14:9	require 158:17	restrict 225:6	208:9 222:5 241:2
215:13 243:5	reminder 15:13	306:19	restricted 131:19	245:22 247:9
244:3 246:8,14,19	removal 225:5	required 121:9	restrictions 233:4	248:5 270:8,9,9
247:13,21 248:8	repetition 35:10	225:11	result 288:22	270:11,12 272:3
248:10,15 249:10	replace 56:21	requirement 8:18	326:19	273:9 279:14,15
250:17,21 251:3	125:6 165:10	requirements 7:15	resulted 18:21	279:17 280:1,3,9

280:19 281:18	revisit 309:10	320:18 322:18	room 10:9 12:12	315:9 318:18
282:7 285:1,1,2,5	rewording 190:13	323:12,16	14:5 108:8 216:8	321:6 322:10,12
285:6,10 286:5	riboflavin 302:9	rising 332:14	Rosado 253:8,10	322:21 323:7,19
287:2,10,12,15	305:21	risk 18:5,7 27:7	Rossner 273:17	savings 119:6
288:7,17 290:9,14	rich 161:14 302:6,8	31:11,12 51:17	rules 8:10,12	saw 34:13 43:5
290:15 291:1,14	rid 115:10	78:18 107:15	ruminant 219:19	77:14 102:15
291:18,20 292:7	right 30:1 33:14	143:17 156:11	220:4,10 222:11	103:22 110:6
292:10,11,21	34:16 55:15 56:16	157:16 158:11	222:15 224:2,19	121:12 132:5,9
295:15,15,16,19	57:3 59:21 67:13	159:7,22 160:14	225:2,5,12 226:8	197:1 223:4
296:2,3 297:10	69:14,15 70:15	162:22 164:22	226:14,15,16	253:20 261:13,15
298:10 300:4,9,10	83:15 87:8 88:9	165:15,15 166:4	ruminants 226:17	281:3
301:10,11,17	90:21 97:19,22	166:14 168:18	run 87:22 88:12	Sawyer 6:2
303:1,5,16 305:13	104:18 106:8	169:14 171:12,18	315:18	saying 108:4
312:4	110:9 117:15	172:12 173:20	Ruxton 107:9	141:10 187:12
reviewed 16:20	123:21 126:2	174:2 175:10		189:18 226:4
18:19 21:10 26:5	129:13 134:17	176:12 178:10	S	318:6 319:14
32:20 44:1 58:18	138:8 139:21	179:4 180:5,14	safe 324:12,15	says 53:6,9 55:15
100:10 139:16	144:11 145:17,20	182:7,12 193:19	328:16,22 330:2,5	124:2 168:20
157:11 179:17	151:18 152:18	195:22 209:8	330:13	187:14 318:1
197:11 243:22	153:7 168:6 169:6	219:4 225:15	safety 123:17 192:4	321:2 323:3
245:4 295:9	170:16 188:10,15	227:7 228:3,9,14	192:4 200:4 203:3	scale 121:20
298:18 303:4	195:3 201:7	233:6 246:12,19	204:4 234:3	ScD 1:19
310:9	218:11 219:15	251:12,17 252:5	325:14 330:2	scenario 233:16
reviewer 17:7	226:10 233:14	294:9 332:17	331:16	235:7,10
reviewing 14:8	252:6 265:8 277:7	risks 158:1 163:9	salami 53:1	scenarios 233:22
298:17	277:18 309:8	164:19 165:22	salt 53:14 209:13	236:3
reviews 16:18 26:1	319:21 322:21	199:19	salts 210:3	scheme 221:20
26:5 39:15 41:17	323:12 327:13	risk-benefit 202:5	sample 17:21	school 250:11
44:14,16 58:19	rigorous 150:10	Robert 2:4 4:10	192:18 206:6	schools 262:16,16
71:20 74:6 75:14	Rimm 1:19 47:4,7	robust 141:3 142:2	satiation 87:11,13	293:8
81:12 99:11,14	49:19 51:3 53:3	145:11	135:6	science 5:1 14:8
105:17,21 106:5	54:2 55:11 56:9	rod 260:13 261:11	satiety 24:7 71:11	15:6,17 17:5
108:3 113:9	85:4,8 86:17 87:1	Rog 201:14 219:6	111:11 134:2,17	scientific 6:16,18
120:14 135:14	87:9 88:5 89:8	309:17	134:21 135:9,12	9:20 17:16 21:20
138:2 140:11	95:7 114:10,18	Roger 1:16 91:16	136:22 137:15	113:9 280:3
143:5 158:17	124:18 125:20	151:22 153:19	306:21 309:19	scientifically 97:13
173:13 174:7	126:12 143:6	154:17 191:7,9	satisfaction 13:4	scientists 167:15
192:14 211:6,13	150:13 151:5	195:8,12,16 200:4	saturated 156:11	screen 12:3,11,17
223:10 244:1,8,13	154:13 167:12	219:17,20 227:9	157:12,14,20	49:15 202:1 246:1
244:14 268:17	171:2,5 177:20	227:20 228:15	159:1 160:10,12	249:11,14,17,19
270:5,6 289:22	178:5,18 179:1	233:9	160:21 161:3	249:22 250:18,21
294:14 296:6	185:13 186:20	role 24:5,8 71:10	164:4 165:8,10	screens 249:21
298:3,20 300:1,13	187:12,20 188:3,8	71:11 134:1	166:2 190:16	se 104:20 126:9
301:12 308:18	188:22 189:17,20	135:18 136:3	215:12,12 216:10	142:20 189:6
327:2 328:1 329:3	200:14 233:11,15	295:21 301:19	216:10 229:1,7	seafood 26:16
revised 231:12	262:3,4 263:2,7	302:16 306:12,15	230:5,14 237:3	154:15,15,18
revising 231:9	317:17 319:4,21	307:9,20	286:12 306:4	156:2 171:10

172:15,19 173:15 174:22 175:5,9,15 177:11,16 179:11 186:7 187:6,7,17 187:18,21 188:3,4 191:4 192:8 194:15 195:9 200:6 205:11 233:10,21 234:6 234:10,10,18 235:1,5,11 236:10 237:9,10 238:4 seafoods 172:9 174:16 seafood-derived 171:10 173:15 175:1,10 177:11 187:15 188:14,16 189:15 search 17:15,16 24:19,21 25:11 57:12,13,18 58:21 59:13 62:1 68:4,9 68:20 74:2 118:1 151:12 158:2 205:20 250:17 254:14 268:16 279:15 324:17 searched 332:7 searches 73:19 172:4 second 38:11 45:12 58:4 73:11 155:17 156:17 159:10 161:5 171:15 175:7 235:7 245:8 262:11 270:19 272:9 275:22 284:19 secondary 139:19 175:12 183:12 Secretaries 6:13 7:2 secretary 5:21 6:9 9:8 section 37:22 57:4 57:5 64:1 80:9	99:9 100:10 115:8 117:13 128:1 140:3 142:7 190:4 190:5 211:16 310:13 316:12 sectional 36:11 41:19 106:3 299:21 sector 243:12 sectors 259:9 see 12:3,17 19:19 20:6 26:22 28:9 28:13,17,21,22 29:4,6,9,17,18,20 29:21 30:20 31:3 31:21,22 32:2 33:2,4,6,14 34:6 34:16 35:8 36:17 40:6,17,21 42:2,9 43:2,8 44:1,7 45:14,19 49:13 50:9,10 54:18 56:7 57:19 59:3 60:3 63:20 65:2 72:2 77:4 78:5,8 78:20 80:3 81:12 82:15 83:22 88:6 89:6 97:6,8 101:12 102:20 103:3,12 104:12 106:1,7,22 110:12 110:15 124:22 126:1,20 131:11 131:21 133:1,10 137:9,14 138:9 139:7 148:10 151:2 157:11,17 158:8 159:3,11 164:1,15,20 178:9 178:15,15 182:6 190:20 191:7 192:1,17 193:12 194:12,22 201:4 205:21 207:19 208:2,16 211:10 212:7 220:19 225:9 226:8,22	227:4 229:17 231:5 232:10 236:2,11,15 239:3 244:19 250:19 252:2,3,7 253:21 273:15 282:17 286:8,20 291:15 298:13 319:13 323:2 324:17,20 327:1,11,13 328:10 329:12 330:15 seeds 235:12 236:6 236:16 seeing 5:14 50:12 64:11 85:14 seen 12:11 82:9 94:20 108:15 124:16 129:3 164:7 183:21 224:17 243:1 246:15 selected 23:11,13 23:18 39:3,22 40:4 71:2 332:2 selecting 231:9 selenium 190:3 237:6 self 246:2 self-monitor 258:3 self-monitoring 257:18 258:1,7 263:17 semi-solid 130:19 send 12:14 senior 6:7 sense 49:1 93:7 99:5 112:14 127:7 127:12 186:17 213:13 sensitivity 206:10 sentence 242:22 separate 12:9 25:2 38:8 53:18 55:14 55:22 57:4,5 192:21 separated 132:4	142:16 separately 26:16 26:17 53:20 75:2 298:19 separation 55:1 September 285:3 series 240:15 serum 166:5 180:16 209:8 212:7 225:1 306:9 serve 248:22 served 53:19 209:12 248:20 service 5:1,11 9:17 10:1,2 319:22 services 1:4 5:6,13 9:10,16 147:15 serving 78:16 96:12 172:20 servings 78:14 147:16 172:18 174:10 175:15 194:15 195:10 234:15,20 236:5 237:18 302:18 306:1 SES 260:17 261:1 session 16:9 324:2 333:1 sessions 154:7 241:18 set 73:3 85:18 86:2 86:18 90:21 100:21 106:17,22 153:12 172:7 235:6,11 265:8 sets 95:5 setting 103:2 310:18 settings 104:9 135:1 seven 15:14,16 24:8 32:20 34:3 40:1 75:14 193:6 222:16 224:6 271:6 276:7,12 291:4,15 300:9	SHANTY 2:1 shaped 332:14 SHARON 1:17 Shelley 89:20 Shelly 92:15 112:10 115:16 139:4 141:10 142:14 185:6,14 198:2,16 199:5 204:7,11 265:12 277:4,9 Shelly's 114:11 116:9 shied 189:9 shine 114:20 Shirley 153:22 188:9 short 121:16 168:7 210:7 274:8 shorter 189:4 shorter-term 326:18 show 31:9 33:21 84:16 111:14 121:18,21 128:21 138:1 222:10 254:3,9 258:14 276:12,15,19,22 313:8 showed 47:16 257:10 258:15 276:21 showing 143:15 185:12 195:20 212:10 270:14 305:14,15 327:15 328:11 329:13 shown 306:3 307:13 309:13 shows 35:12 160:11 187:9 229:15 265:6 shuffle 60:15 side 11:18 33:14 57:14 162:18 166:9 198:19 261:13
--	--	--	--	---

sidewalks 244:21	sixth 15:9	40:3 41:10 42:3	slides 22:22 138:1	229:21 230:1,11
signal 144:18	size 115:1 192:18	42:15,22 43:1,14	153:12	231:21 232:6
200:20 310:2	206:6 248:11	43:21 44:9,18	slight 201:5 237:7	235:14 247:7
signaling 309:19	264:3 273:12	46:1,22 72:5 73:2	slightly 293:13	284:18 289:18
signals 306:22	sizeable 157:22	73:15 74:10 79:11	slowing 306:20	294:8 316:19
significance 98:11	sizes 17:21 18:1	79:21 80:17 81:10	small 39:12 44:11	solids 130:4,8
significant 86:4	246:1 247:6	82:18 84:19 99:17	81:15 88:7,9	132:10 133:7
90:5 119:10,12,21	248:15 259:18	102:22 104:18	98:14 115:3	soluble 232:13
131:16 169:19	265:3	108:12 110:16	135:10 146:9	somebody 67:7
223:15 227:22	skills 201:2	112:5 117:15,16	213:19 215:3	131:9 204:8
273:3 283:7	skin 229:14	118:2,14 133:17	217:1,5,5,9,10	somewhat 121:5
293:14 295:21	skip 251:16	134:9 135:17	223:6 224:20	201:2 222:5 324:5
299:20 301:19	Slade 6:1	136:10 138:4,15	229:21 230:2	sorry 67:22 85:7
304:10,15 309:8	Slade-Sawyer 2:3	138:20 154:4	248:20 269:8	127:14 145:22
significantly	9:4,6,7	159:4 171:7,20	273:13,21 274:5	233:13 263:7
119:17 165:14	slash 327:14	174:13 175:7,13	284:4,10	299:11
228:2 279:2	Slavin 1:19 22:16	176:3,9 177:4	smaller 18:3 98:17	sort 17:15 45:3,13
similar 34:15 44:4	22:20 47:6 49:5	178:1 179:16,21	247:4 249:1,2	48:14 58:5 60:15
63:14 82:2 89:6	50:18 51:9 52:13	179:22 181:3	smoke 321:7	60:21 61:6 65:2,3
100:12 210:20	53:22 55:8 56:3	182:9,13,20 183:4	smoked 55:4	80:7 89:9 113:10
290:16	56:11 57:3,11	183:8 184:5 190:9	snack 85:22 90:11	117:1 127:3,17
similarly 204:6	58:15 59:3,12	193:4 202:22	209:13	139:14 143:11
208:12,19 248:4	61:21 63:1,10	206:18 207:13	snacking 246:2	144:3,12,12 145:2
simple 251:18	65:5 67:5,20 68:2	208:18 209:2	254:13,17,19,21	146:6 150:14
simply 12:20	68:8,13 69:1,14	210:22 211:9	255:3,6,8,15,18	166:10,20,21
274:10	69:18 70:15 85:17	212:20 214:9,21	256:6 257:2	173:22 178:3,20
Simultaneous	86:19 87:8,16	215:2 221:22	259:12,14	186:19 198:2
126:11	88:15 89:18 91:17	222:18 229:15	snacks 317:11,14	203:2 205:6
single 169:16 313:7	91:21 92:1 93:6	231:16 235:15	snuck 188:14	244:21 245:12
site 5:17 142:10	95:2 96:5 97:3	236:1,21 242:2	socioeconomic	262:7 265:4,5
sits 200:4	112:12 114:1,17	243:21 245:5,7	266:14 267:4	266:10,13 312:14
sitting 48:11 143:2	115:6 117:12	248:9 249:3	soda 114:13,21	316:8,18
249:20	122:19 123:15	250:13 251:2	sodas 113:5	sorting 78:5 162:20
six 24:5 30:12	127:21 128:8	252:1 254:6,12	sodium 16:3 49:12	sound 97:13 226:3
31:13 35:4 40:2	130:1 136:20	255:11,21 256:4	210:5	sounding 218:1
41:17 42:4,7	137:8 138:8	257:15 258:19	soft 100:22 101:14	sounds 88:11 217:4
44:15 117:6	139:22 141:8	260:5 274:14	101:16,17 107:22	218:3,3,6
131:16 164:1	142:6,22 144:16	283:9 287:13	108:21,22 109:21	soup 131:19 133:3
173:12 179:9	145:17,21 267:12	288:20 292:10	110:3,4,7,7	133:3,8,11 134:5
197:17 269:15	268:2 277:3	293:15 295:17	121:15,15	134:5,7
270:15,17 271:6	slide 20:6 23:1,4	296:6 297:8,22	sold 210:3 243:8	source 61:16 95:11
271:10,18 272:16	24:18 26:8,20	298:8,17 300:7,12	solely 146:20	100:7 106:12,15
273:7 278:20	27:18 28:6 30:7	301:16 302:21	147:11 182:22	106:19 184:11
285:11 286:5	30:14 31:6,16	305:11 324:16	solid 24:3 71:8	186:9 203:7
291:19,21 292:18	32:12,21 33:18	325:3 326:2,9	113:3 130:9,13,14	209:21 213:8
300:14 305:4	34:5,21 35:6,19	328:14 329:1	130:19 131:7,14	294:10 301:22
326:17 328:17	37:1,17 38:16	330:3 331:17	133:15,19 216:7	302:3,7

sources 20:14 37:3 37:12 44:8 46:4,6 46:13,15 48:9,9 92:18,20 93:2 96:18,20 97:16 113:1 166:15 171:2 181:6,13,20 182:17 183:15 184:2,22 185:8 223:13,22 238:10 242:16 293:17 294:7 295:2 302:9 316:21	spread 183:7 stable 160:22 stack 186:19 staff 10:7,9 12:12 12:19 14:2,22 23:4 26:2 28:8 153:21 234:1 240:20 stand 142:18 standard 83:21 90:21 standardizes 17:8 standards 87:20 330:7 standing 4:5 standpoint 213:12 starch 103:7 104:14 111:21 116:1 150:22,22 152:2 starchy 151:16,19 152:4 start 23:6 47:5 100:14 125:11 140:7 152:19 170:9 185:3 239:8 started 74:1 104:22 174:15 191:18 201:22 starting 25:7 274:22 starts 64:16 138:17 150:14 state 7:3 13:14 14:8 217:1 stated 190:13 199:1 statement 20:3 68:10 94:9 141:16 160:1,5 161:16 165:4 170:7 172:17 181:2 188:7 197:21 200:17 202:20,22 203:13,17 209:3 212:16 214:14 217:7 274:11 284:3 292:4	statements 15:1 21:3,14 52:6 67:18 145:15 186:2 197:16 States 1:1 4:7 14:11 280:21 static 52:20 stating 168:21 190:18 statistical 269:4 statistically 131:16 status 242:13 244:11 stay 25:16 66:15 257:1 319:20 staying 255:10 stearic 213:5 215:17 216:2,3,13 229:8,8 Steffen 35:13 42:10 step 17:13 steps 168:6 314:1 sticky 128:19 stomach 41:7 stomachs 239:1 Stookey 109:9 stores 242:20 243:16 244:16 straightforward 251:18 strategies 174:21 184:11 284:14 strategy 24:19,21 146:15 177:9 185:2 268:16 324:17 stratify 316:4 streamed 13:13 streaming 12:21 strength 197:15 261:3,11 312:12 stress 176:20 stretch 9:14 strictly 183:4 striking 49:3 266:1 STRIP 285:15 286:7 306:11	321:5 stroke 174:5 strong 14:15 20:4 64:14 91:12,13 93:19 139:6 143:3 176:15 181:2 186:3 189:11 196:13 200:16 233:17 246:10,10 247:21 248:3,9,14 249:13 250:21 257:20 261:8,12 282:11 284:5 311:12 316:10 319:11 stronger 25:21 47:14 48:2 50:16 74:1,19 79:17 83:4 89:15 111:7 131:13 138:5 139:20 141:5 148:2,4 200:20 201:4 242:22 243:4 251:13 283:18 288:8 294:15 308:20 310:2 313:6 strongest 25:15 60:21 74:3 84:1 93:13 94:3 172:9 176:3 246:14 249:16 264:6 strongly 170:7 277:15 structure 133:22 267:1 struggled 65:7 91:10 170:17 189:12 stuck 139:14 studied 285:15,21 286:15 288:14 291:7 292:18 296:11 304:12 studies 17:19 18:11 18:18,18 19:1,2 19:20,21 25:12,15	25:17,18,19 26:4 27:5 28:4,9,10 29:9,13 30:2,10 30:13,17,18 31:9 31:15 32:15 33:3 33:21 34:7,10 35:4,10,11 36:5,8 36:14 38:4,6,7,21 39:6,18 40:2,8,14 41:16,19,20 42:12 43:6,12 44:3,4,22 45:1 46:9 47:10 47:16,21 49:7 50:7 52:14 53:1 54:18,22 55:13 56:5 57:15 58:7 59:22 60:1,2,12 60:19,22 61:5,9 61:17,22 62:2,6,8 63:15 64:7,21 65:10 66:15 67:4 67:10,14 68:6,16 69:9 73:20,21 74:1,7 75:18,20 76:16,18,19 77:1 77:22 80:21 81:1 81:5,6,15,18,18 81:19 82:2,15,20 82:21 83:1,6,14 84:12,14 87:12 89:6 91:19 92:3,3 93:10 94:4,20 98:19 99:13,15 100:4 101:2,5,9 101:10,12,20 102:19 103:4 104:19 105:13,19 106:2,3,4,17 107:4,12 108:13 108:19,20 110:18 110:22 111:4 112:15 113:7,13 113:15 114:6,19 118:8 119:1 120:10,13,18,19 121:5,12,14,17,18 122:9 123:4,18
--	---	---	--	--

125:17 126:6	275:10 279:19,19	88:16,16,17 91:5	22:14,15,18 24:15	61:8,10,14,19
131:4,5 132:2	279:20 280:9,11	93:15 101:4,14	50:20 66:12	86:18 158:22
133:1,3,3,22	280:12,18,20	102:2,8 103:5,16	137:10 153:10,13	170:5
134:12,22 138:3	281:3,19,20,21	103:18 104:2	153:17 199:7	substitutions 157:7
139:2,15,18 141:4	282:3,13,17 283:5	107:9,19 108:20	203:15 239:16,19	157:12,17 159:2
142:2,3 143:3	283:12,18 284:4	109:6,6,16,21	239:22 251:8	170:13
144:5,15,19	284:11 285:11,13	110:5,14,19	277:10 318:13	subtle 311:17
145:11 147:1,6,14	286:5,19 287:1,2	113:11 114:4	324:4 333:5	sub-group 129:12
149:5,14,15 151:6	287:11,15,21	116:7,13,14	subcommittees 8:1	sub-question
158:12,15,16,21	288:9,10,10 291:2	119:20 122:20	15:14,16 17:9	284:19 290:8
159:1,13,17,21	291:3,13,20 292:1	123:6 125:22	21:18 52:3 60:11	302:22
160:3,19 162:11	292:8,13,14,15	126:3 131:15	65:22 66:18	successful 14:6
163:1,19,20,22	294:16 296:4	132:4,8,11 133:10	Subcommittee.153	128:11 328:20
164:2,7,19,21	297:11 298:10,12	135:7 143:9 144:8	3:5	succinct 16:17
165:14 166:7	298:21 299:1,2,8	147:11,19,19,20	subgroups 148:12	sucrose 102:11,12
167:1,7 168:3,4	299:10,12,21	148:7 151:12	233:6 235:16	103:7,8,9 104:3,5
172:4,5 173:8,10	300:3,8,11,14,21	157:16 158:11,19	317:1	104:6,14 111:9,13
173:22 174:3	300:22 301:1,6	159:10 162:4	subject 129:9	306:5
176:5,6,11 177:2	302:10 303:9,17	165:15 168:5	182:13	sudden 173:2
178:8,12 179:18	303:18 304:12	178:13 180:3	subjects 17:20,22	175:18 180:10,20
179:19,20,22	305:13 307:5	182:15,21 183:7	18:12 80:14	180:20
180:9,11,12	308:16,18,21	183:12 200:21	160:17 171:18	suffer 314:18
181:10 183:11	309:9 310:9,15	201:7 208:14,22	172:15 179:5	sufficient 73:22
184:3 185:12,14	311:5 312:19	211:8,9 212:1,4	326:7	179:13
185:16 192:13	314:4,11 316:2	223:5,7 226:6,7	submitted 176:9	sugar 85:13 87:15
193:3,6,7 194:11	317:4 318:17	228:6,8 249:9	submitting 6:22	98:3,7,11,15,22
196:15,16,22	319:6 325:19	252:12 253:8	subsampling 285:21	99:9,21 100:2
198:21 199:8,9	326:3,6,6,18	254:9,18,18	287:5 288:13	102:6 103:1
206:3,4,14,20	327:3,5,7 328:2	257:10 271:19	291:6 292:18	104:20 105:8
207:2 208:9 210:9	329:4,4,6,8,13	272:9,14 273:6	subsequent 134:4	106:11,18 108:17
211:4,5,15 212:10	330:16,17 332:18	275:14 280:15	138:20 182:7	111:3,16,19,22
212:12 214:20	study 17:22 25:21	281:6,6,9,11	subset 156:21	113:5 114:2 116:3
216:4 221:6,9,13	31:18,20 32:22	282:20 285:17	substantial 223:20	116:19 117:1
222:3,3,4,19	33:17 34:8,18	286:7,8,9 293:1,7	236:22 237:2	120:6,8 121:13
223:6,11 224:5,10	35:13 36:7,11,11	296:22 297:9,15	242:7 308:16	122:4 123:6
243:4 244:3 246:6	36:22 39:11 40:3	297:19,20 304:5	substantially	125:14 129:18,21
247:10,20 248:2,6	40:9,19,20 41:5,6	306:11 313:5,7	269:21	136:16 137:20
249:4,6 250:20	42:4,10,22 43:2,3	314:6 316:8 321:5	substituted 118:5	138:6,10,18,20
254:3,10,16	43:6,9,17,21	328:2,4,6 330:17	118:20 119:4	214:18 247:7
255:22 256:2	44:17 56:8 59:7	330:19 331:2	123:11 156:11	294:11 315:9
257:6 258:16,18	59:18 60:6 62:13	332:16	236:10	316:22
260:14,22 261:7	62:20 73:18 75:22	study's 18:14	substitutes 127:11	sugars 98:7 100:5
264:2 267:15,18	77:5 78:2,13,14	stuff 50:22	substituting 34:11	110:18 111:1
269:3 270:13	78:22 79:4 80:12	Stunkard 281:6	34:15 61:10 86:15	113:2,3 114:5
271:1,3,6,10,20	81:13,20 82:2,8	subcommittee 3:4	157:10 232:5	117:16 142:20
272:2,4,20 273:1	82:10,14 86:9	3:6 15:17 16:3	235:4	230:1 284:18
273:17,18 275:7	87:19,21 88:10,11	19:8 21:7,13	substitution 40:20	294:7 315:9

316:19	22:3 42:2 43:1	198:10 261:19	317:1	systems-related
sugar-sweetened	142:9	supports 38:18	sweetener 102:13	245:13
23:20 24:12 71:3	summarizes 298:9	109:8 142:3	112:8 123:7,11,16	systolic 42:1,6
98:20,22 99:19,22	summarizing 219:7	148:14 274:2	123:20 124:21	
100:5 105:13,16	summary 13:7	290:18 294:16	125:2	T
107:7,14 108:5	63:16 168:19	supposed 65:1	sweeteners 24:1	tab 109:22
109:7 110:4,20	172:7 229:18	86:20 87:10 239:8	71:7 111:10	table 28:20 30:15
111:5 112:18	237:9 305:12	253:14	117:17,17,22	31:17 34:6 63:16
113:16,20 114:15	supermarkets	sure 52:17 60:20	118:5,9,11,17,19	116:22
115:4,10,17	242:15,17,18	64:1,2 67:8 69:6	119:2,4 120:5,12	tables 56:7 168:19
116:11,21 119:5	244:10	69:10 93:1 97:3	120:15,18 121:1	169:2
122:13,22 123:8	supplement 185:12	114:9 125:17	121:10 126:7	take 21:8 37:21
123:10 124:21	185:14,16 186:13	135:21 142:11	127:8 128:5	47:1 61:2 65:15
128:21 129:18	192:22 198:3,7,19	144:20 199:20	129:10 241:20	79:11 85:1 86:2,6
137:22 138:16	199:8,9,22 201:22	203:18 204:8	sweeter 126:8	115:21 120:6
140:8 142:4,19,20	203:7,14 296:20	214:4 234:21	switch 123:20	130:2 133:16
143:13,15 293:6	304:6 314:7	239:1 240:14	124:2,3	140:15,16 145:22
311:19 312:8	supplemental	263:8,18 277:3	switched 311:22	152:20 188:17
313:2 315:10	201:13	308:20 321:6	syndrome 157:2	223:18 230:18
316:16 318:10	supplementation	surplus 284:15	208:5 221:12	232:20 238:9
suggest 32:16	198:4,12,13	294:9	synthetic 155:8	239:7 240:1
38:22 39:7 42:12	204:16	surpluses 289:19	220:10 221:3	243:10 262:6
42:17 64:21 98:19	supplemented	surprised 97:9	systematic 17:6,10	264:5 269:11
120:14 150:8	297:2	225:18 261:3	19:10 20:10 21:11	315:11
172:11 204:16	supplements 175:6	surprising 101:22	26:1 39:15 43:19	taken 52:3 162:7
224:1 226:11	177:3 185:9 186:3	surprisingly	43:22 44:14,16	227:21 256:21
233:17 255:3	186:21 187:10	103:12	58:19 75:14,22	takes 19:20 45:9
302:10 320:4	188:16,17 198:22	surrogate 75:10	77:12 79:18,19	127:8
325:20 327:19	199:1 202:9	288:3	80:1,4 81:1,2,11	talk 24:21 47:2
suggested 102:5	supply 128:5 185:2	surrounding 202:6	99:11,14 105:17	49:15 51:4 71:5
suggesting 126:6	241:16	survey 13:3	105:20 106:5	71:14 75:19 84:22
149:20 183:18	support 4:17 8:17	surveys 21:20	108:3 138:2 139:1	87:4 89:20 96:8
190:14 202:10,12	10:11 12:6 14:2	suspect 238:21	139:17 140:11	101:10 151:14
310:21 322:6	14:22 99:14	sustained 326:21	143:5 158:17	154:18 155:4
suggestion 181:1	108:22 109:11	Sweden 28:6	172:1 173:13	168:5 206:15
232:7 310:12	118:10 119:1	sweet 125:4	174:7 176:19	209:11 218:18,19
322:4	127:3 130:12	sweetened 98:8	179:19 192:14	218:21 233:10
suggestions 182:2	191:8 250:3,8	99:10 100:3 102:4	206:19 207:4	268:7 317:19
277:2	280:4 289:22	102:7 103:19	208:9 222:5	talked 55:3 87:2
suggests 39:19	301:13 303:12	106:12 108:18	243:22 244:14	143:9 200:10
74:16 79:14 94:10	318:19	109:10 114:3	247:9 248:5 296:6	265:12 311:20
147:2 284:13	supported 16:11	116:20 117:2	298:3 301:11	318:12
285:7 288:17	161:10 197:21	119:22 122:3	308:18 327:2	talking 51:19
suited 149:8	supporting 15:2	125:14 129:4	328:1 329:3	154:22 160:20
sum 274:2	19:17,22 21:15	138:11,21 290:12	systematically	167:9 174:9 177:1
summaries 15:2	306:13	290:20 292:5	150:20	185:3 188:12,13
summarized 16:18	supportive 159:21	294:10,20 311:17	systems 259:6	189:19 195:9

215:21 216:1	terms 52:7 58:21	306:17	114:2,10,18	250:22 251:18
228:22 240:3	60:13 127:3	therapy 18:12	115:14,16,22	252:11 253:13,15
320:13 333:7	129:20 150:11	thereof 244:9	116:17 117:12	253:16 254:14,21
talks 168:12	155:11 156:6	there's 255:13	121:8 122:8,11,14	255:1,4,6,20
target 129:7 144:11	157:15 166:12	thiamin 305:21	123:3,12,15,19	256:2,9 257:13
233:5	169:18 170:22	thing 29:8 30:18	124:19 125:8,16	259:4 260:4,12
task 146:4 166:11	192:2 198:11	34:14,15 48:19	125:20 126:3,4,18	261:20,21 262:1,4
taurine 190:2	212:6 224:22	52:20 82:8 84:6	127:15,18,18,22	262:19,20,20,21
teach 127:14	227:2,3,5,5	111:3 116:15,16	128:8,19 129:8,15	263:5,9 264:7
team 8:15 191:12	247:21 250:2	132:14 134:12	129:21 137:5,8,14	265:4,22 266:6,17
204:3,4 220:21	254:12 256:14	140:7 143:21	139:4,6,10 140:3	267:19 277:5,9,13
229:19 309:18	257:6,18 265:2	245:8 320:16	140:13,20,22	277:16,19 278:2,4
teams 204:5	275:2 312:5 316:6	330:1	141:1,12,21	288:1 309:6,22
tease 198:18	318:6 323:4	things 30:22 47:12	142:17 143:2,6	310:8,18 311:11
technical 7:1 10:10	terrific 153:22	49:12,22 50:21	144:5,11,16 145:1	312:2,4,7,18
12:1,4,5,9,15	260:11	51:2 52:1 53:15	145:14 148:14	314:10,18 315:17
15:19 332:22	tertile 293:2	53:16 55:5 56:19	151:18 152:9,20	316:1,9,12 317:2
technology 11:2	test 102:5,10	83:7 85:20 86:16	153:20 164:10	317:4,21 318:5,13
tech_issue@yaho...	126:13	87:4 88:2,14	166:16,17 167:5,8	318:15 319:5,9,16
12:18	testing 188:6	114:14 144:1	167:13,14,15,15	319:17,18 320:8
teenage 91:20	226:17	183:1 189:8 190:2	167:19,20 168:2,6	320:15 321:13,22
television 249:17	text 266:5	220:16 223:1	169:4,18 170:6,12	322:4,5,8,21,22
250:1,2,7,10	th 4:13	236:15 241:12,22	170:16 175:19	323:5,14,22
255:13,17	thank 4:4 10:16,17	244:20 265:4,16	176:2 177:12	thinking 50:19
telling 90:2,12	13:22 23:2 63:3	287:20 319:17	180:22 181:8,22	51:18 68:14 84:9
123:1	66:21 68:8 92:12	think 22:21 26:22	182:1 183:11,12	89:9 133:14
temperature 133:5	94:6 137:17 152:1	47:1,11,13,22	184:22 185:22	175:21 252:10
216:8	153:2,14,17,20	48:4,5 49:5,16,19	186:4,8 187:7,10	thinks 313:10
temptation 129:4	171:5 178:22	50:15 51:1,14,16	188:10,20 189:2	third 18:15 73:12
ten 206:6 282:1	191:10,11 195:14	52:2,5,13,20 53:9	189:11,13 191:6	82:9 113:2 235:10
298:9 299:8 328:2	196:6 216:16	53:17 54:4 55:13	191:22 192:3	269:12 272:14
tend 77:1 89:4	238:16 239:5,10	55:21 56:3 58:13	196:18 198:3	290:8 317:18
98:16 121:3 126:8	240:14 274:15	58:15 59:8,13,17	199:12 200:3,5,7	thirds 281:20
223:9 242:22	275:17 276:4	60:8 61:11,14,21	200:8,10,15,18	282:13
243:19	278:5,6,10 308:4	62:8 63:19 64:6	201:6,8,11 202:19	Thirteen 211:5
tended 25:16 66:14	309:17 311:14	65:5,16,19 66:6	203:5,6,11,17	Thomas 1:17
183:5 223:8	323:20,21 333:8	66:11 67:12 68:16	204:13,18 205:9	153:14 154:1
tends 93:11 95:5	thanking 4:16	69:1 70:10 78:3	205:10 208:15	167:8 168:2 169:1
280:4	thanks 152:14	85:9,21 86:19	209:22 214:9,11	170:14 184:7
term 56:21 57:13	178:17 189:17	87:1,16,22 88:5,9	215:3 217:3,12,14	189:21 190:11,19
116:16 121:8,16	190:22 219:21	89:9,14,22 90:1	217:21,22 218:20	191:1 195:7,15
126:16 129:17	220:20 234:1	91:4,11,12 92:4,5	219:3,7,8,16	197:12 200:3
147:6 177:14	268:3	92:5 93:16 94:17	227:18 228:16	203:4 205:8 214:1
189:5,5 218:16	theirs 63:12	95:2,12,13 96:2	232:18 233:11,16	214:4,7,19 215:6
219:9 311:21	theoretically 120:8	97:10,17 104:10	238:15,18 240:1	215:15 217:14
324:13,15 325:14	121:18 124:4,7	105:3 110:9,11	244:18 245:12	218:7,13,20
330:5 331:16	128:11 288:22	111:16 112:20	247:11,14,17	219:15 225:17,22

227:9 228:15	132:3 134:19	191:11 198:20	146:22 147:4	266:20
233:13 238:13	136:12 137:10,12	213:22 216:18	155:15,16 165:11	translational 16:7
thought 27:3	143:19,21 144:6	219:7,22 225:19	170:18 173:8	transparency
126:17 129:2	145:22 148:22	238:20	179:10 199:14	10:18
138:10 143:12	152:9,22 200:22	tomato 147:11	208:7,14 213:19	transparent 7:19
144:8 179:2	201:20 205:1,9	tomatoes 147:14	217:2 225:8 229:4	8:19 17:6
191:17 220:7	210:7,19 219:16	tomato-based	229:5,7 230:14	trans-fatty 155:8
253:9 263:13	224:14 238:16	147:21	236:7 237:2 250:5	165:9
three 24:10 34:11	239:9,15 240:2	tomorrow 8:3	273:4 279:11,12	treads 61:6
36:2 42:20 53:16	245:3 246:1,17	11:13 16:10 22:7	280:5,13 281:1,7	treatment 18:11
75:15 78:14 81:4	247:12 249:8,11	51:16 112:22	281:22 282:8,10	81:17 293:15
100:20 101:9	249:14,17,19,22	151:13 152:11	284:1,9 285:19	304:9
103:6 105:17	250:5,18,21	192:5 204:12,18	286:2 287:3	treatments 131:7
107:4 119:7	254:19 257:8	251:6,22 277:12	288:12,22 289:5	tree 209:5,16
124:20 125:22	264:21 265:17	277:20 314:22	289:16 290:1,2	tremendous 56:15
126:13 138:2	269:20 282:9	333:2	294:6 297:5 305:7	trends 254:19
147:13 155:10	286:16 290:9	tomorrow's 16:9	306:4 310:13,19	trial 36:6 44:17
157:19 159:13	303:12 306:19,21	Tom's 202:13	315:8 321:3	45:19 50:4,5 62:3
161:9 172:19	307:8 313:17	219:11	322:22 326:2	62:15 75:16 78:10
176:5,10 179:20	317:18 324:1	ton 123:17 202:19	329:21 330:8	79:21 80:13 81:3
194:16 206:21	326:21 329:18	tool 274:12	totality 143:8	81:14 85:5,14,16
207:4 211:6 222:3	333:3	tools 110:22 115:14	totally 115:9	86:17 88:12 102:1
222:18 224:9	times 28:14 37:16	128:9,10,14 140:5	322:12	102:9 110:7
228:18 233:22	65:8 86:22 87:2	282:9	tough 125:18 144:4	116:14,16 119:16
234:5,19 235:6	133:8 135:9	top 34:18 43:2	towns 262:20	122:7,11 124:9,19
236:9,10,14	204:14 207:21	75:22 79:22	track 204:8	125:21 126:21
237:18 244:5	218:22 222:16,21	108:19 158:21	traded 157:20	127:1 132:20
255:14,17 256:15	224:8	287:16 291:15	trading 164:22	139:18,19 163:12
269:13 271:17	tiny 241:3	293:2 298:12	traditionally	182:22 183:4
272:4 273:1,7	tissue 304:3	topic 3:4 15:15	301:22	189:5 199:22
280:11,22 285:14	tnutrition 9:21	22:18 72:4 134:10	training 125:1,3	206:21 207:5
285:18 286:20,21	today 5:15 8:3	146:16 154:20	129:14	208:21 217:16
291:7,17,20 292:1	11:13 12:3 14:4,5	191:2,13 205:3	trans 157:21 166:2	275:10,12 276:8
296:5 298:2,2,5	16:10 22:7,21	219:18 247:11	190:16 219:19	285:13 286:1,6
299:1 301:2,11	51:16 66:17 69:21	topics 70:19,20	220:1,4,11,17,21	291:9,14 296:7,8
302:4 303:18	70:22 146:4,8	72:1 137:9 154:3	221:1 222:11,15	303:21 305:15
304:11 330:16,17	152:20 240:16	154:6,11	222:21 223:13	321:5,7 329:15,16
330:17	260:9 303:1	topic-specific 8:1	224:2,15,19 225:2	trials 19:5 42:20
threshold 178:4,7	315:14 332:22	tortured 139:12	225:5,12 226:4	44:3 58:8,10,14
185:21 312:15	today's 195:4	total 15:22 20:22	227:13	61:8 66:14 73:1
throw 126:4	tolerance 161:21	28:14 29:5 30:19	transcript 13:6,9	74:19 75:9 78:12
throwing 85:7	162:12 308:2	32:2 33:1,3 35:11	transient 269:8	79:17 81:4 100:20
tighten 90:9	tolerated 161:15	35:14 39:12 44:11	271:17	105:19 109:13
time 12:8 16:14	162:11	51:12 52:7 59:6	translates 265:20	121:21 122:14
59:15 80:15 82:9	toll 12:6	59:11,18 92:21	translating 7:4	123:14 158:15
84:22 103:3	Tom 153:11 166:19	96:3 112:14,16,22	52:7	159:12 161:8
109:11 125:18	170:2 190:8	125:10 142:16,18	Translation 245:9	163:21 164:8,16

166:8 167:5,10 173:9,16 175:4 177:13 181:10 183:13 184:3 185:9 186:4,13,18 189:1,4 196:16 198:3,4 206:3,22 207:5,6 209:15 210:6,12 211:8 212:7 218:8 253:21 258:11 261:6,7 264:10 269:2 270:10,13 270:18,21 276:7 292:13,21 296:5 296:11,14,16 300:2,4,22 303:8 303:17,19 308:17 313:9,19 320:21 321:2 327:10,12 328:11 329:15,16 330:1	101:6 106:3 127:5 127:9 134:11 144:5 145:2 167:21 196:10 210:10 218:2,3 264:10 277:4 320:3 321:14 TUESDAY 1:10 tune 66:8 turkey 52:19 53:13 turn 9:3 13:18 115:21 136:17 238:18 turning 245:6 Twenty 327:3 twice 194:16 289:3 two 10:22 19:15 23:9 33:3 41:18 45:12,12 53:15 75:14 79:1 80:15 81:3 82:6 89:18 96:12 105:19 126:1 137:7 143:20 147:8 154:11 155:4 156:7 159:4,17,17 161:9 162:21 172:8,18 174:10 175:15 178:14 179:10 187:16 194:15 195:10 199:13 200:8 203:19 205:2,16 206:1 207:6 212:11 221:10 222:3,4 223:22 232:4 234:15 236:9,13 244:13 246:5 249:20 250:5,7,11 255:22 256:1 261:15 262:6,17 263:9 265:21 266:11 269:1 270:10,13 272:7,19 276:15 276:22 281:2,19 282:12 283:22	285:14,16,22 286:10 292:21 294:22 296:11,14 297:10 299:1,3 303:17,18 310:12 312:12 313:13 326:3,4 328:1 329:6,8,14,16 330:1 two-armed 123:5 two-thirds 96:21 97:1 two-way 5:16 two-year 125:21 type 26:12 27:9,15 29:11,14 30:15 31:17 32:13,15,18 32:22 34:5 36:4 39:2,21 40:9 41:1 73:12 74:18 79:15 84:2 121:21 146:12,15 147:4 148:3,19 149:10 156:8,12,20 159:9 159:18 160:8,15 160:17 161:7,19 163:3,10 164:16 165:16,22 166:13 170:4 180:7,8 181:18 193:14 206:11 225:14 233:7 332:3,10 types 29:7,15 30:19 31:12,21 32:9 33:9 35:16 36:12 36:19 41:20 43:12 53:1 63:12 88:20 101:10,19 102:11 102:16,19 111:8 119:14 121:16 133:21 145:11 152:7 187:16 206:16 207:3 210:11 212:18 227:6 315:17 typical 131:10 220:21	typically 40:12,14 45:6 52:15 60:2 76:16 82:19 83:4 84:13 88:21 100:13 104:21 120:11 121:1 133:6 134:12 140:8 202:3 221:2 typo 106:13 253:16 <hr/> U U 332:13 UK 31:19 78:19 87:20 184:15 ultimately 87:14 unable 4:9 unbelievable 315:5 UNC 254:20 unclear 45:17 273:11 underdeveloped 279:19 undergoing 113:12 underreport 283:21 314:15 understand 20:20 56:10 185:7 198:8 219:9 258:21 259:8 320:19 understanding 169:9 198:4 311:2 undertaken 14:13 unfortunately 4:8 54:16 115:13 289:15 294:5 307:5 314:10 326:5 unintentional 332:19 unique 38:19 46:14 84:3 85:5,15 114:22 uniquely 111:19 United 1:1 4:7 14:10 31:15 35:6 280:20 universal 254:5	unknown 134:8 unnecessary 129:7 unprocessed 49:10 unpublished 101:3 unreasonable 218:12 unregulated 90:22 unresolved 130:13 unsalted 209:4,10 209:16 210:4 unsaturated 306:5 unsaturates 157:22 update 20:13 72:12 118:1 119:7 248:12 249:12 250:14,19 251:1 257:19 275:22 updated 245:21 updating 158:3 172:1 upfront 323:18 upped 78:16 upwards 216:1,13 urban 241:13 Uruguay 11:21 USDA 2:1,1,4 4:12 5:4,11 7:2 16:22 54:6 156:3 229:19 231:19 233:21 235:1 236:4 237:10 240:20 use 18:22 19:1,4 36:8 44:21 53:9 57:8 63:22 78:1,7 83:21 118:8 119:1 120:11 183:1 192:21 211:18 216:9 243:7 250:12 312:4,6 316:2 useful 169:13 usual 45:7 usually 140:9 189:7 U.S 18:17 28:5 30:14,17 31:15 32:21 34:5 35:5 40:16 50:2 93:9
--	---	---	---	--

weigh 105:9	259:1,3,12 268:6	240:4 277:19	147:20	115:20 126:15
weighed 197:14,20	268:13,22 269:7	we're 65:1,17 174:4	wonder 48:6	wrap 146:8
weight 16:1 23:21	270:3,16,18,20	188:12,13 234:20	150:14 262:6	wrapped 177:6
24:1,4 26:13	271:5,9,15,15	we've 31:13 65:5	313:10 322:18	writeup 311:6
27:10 35:20,21	272:5,7,11,12,16	156:7 172:4 173:3	wondered 68:17	writing 16:6 186:1
36:1,12,14 38:15	272:18,21 273:5,7	183:21 191:8	wonderful 5:12	written 8:7 13:7
39:11 43:15,18	273:10,14,22	193:2 198:16	63:4 220:20	wrong 321:12
44:9 45:19 60:2	274:5,13 275:2,3	203:22 205:1	238:21 274:21	www.dietaryguid...
60:13 67:2 70:4	276:10,13,14,20	237:13 240:7	wondering 56:20	8:9 11:9 13:11
71:4,7,9 73:13	283:11,22 284:2	241:17 245:21	64:10 137:4,21	
74:22 76:4 80:17	296:20 297:17	266:10	142:6,22 187:6	X
80:20 81:9,16,22	300:19 304:7,9	we've 65:7	263:19 314:13	Xav 139:11 140:17
82:3,5 86:13	305:8,10 306:16	whatsoever 201:20	word 54:14 195:4	228:5 239:18
88:20 89:4,7 98:9	306:18 307:4	what-if 233:16	217:12	Xavier 1:18 170:3
98:21 99:2 100:3	319:7 320:8 321:9	what's 49:9	worded 68:10	170:14 239:17
100:14 103:1,7,13	324:3,7,9,10,11	wheat 81:19 95:13	196:19	
103:21 104:1,3,8	324:13,15,21,22	136:8	wording 113:18	Y
104:17,20 105:5	325:3,7,8,8,8,18	white 34:18	195:17	Yeah 141:8
105:15,17 106:14	325:22 326:7,12	WHOLEheart	words 9:5 315:11	year 211:2 265:21
106:20 107:8	326:14,15,20,22	78:13 80:12	wordsmith 65:2	272:10,13 305:11
108:1,16,18	327:4,18,21,21	WIC 305:6	141:21 217:4	years 52:19 63:9
109:20 110:15	328:4,8,13,17,20	WIC-defined 305:9	work 5:3,6 7:14	91:20 96:17 109:5
111:18 116:19,22	329:6 330:5,9,9	wide 46:15 157:18	8:17,18,22 14:10	126:1 139:12
117:7,7,18 118:7	330:19 331:5,9,10	widely 63:9	14:13 17:12 21:9	161:1 172:8 192:9
118:10,11 119:2,9	331:10,10,20	wider 149:7	47:8 56:15 66:17	196:22 197:2,5,7
119:10 120:2,9	332:1,2,16,19	WILLIAMS 1:20	87:11 133:14	197:8 205:2 221:7
121:10,11,16,20	weighted 214:15	66:20 67:17 68:15	146:5 149:21	221:10 222:2
123:2,3,21 124:4	welcome 4:14 14:2	69:12 96:16	238:9 245:10	250:8 272:7 286:9
124:7 126:1	153:8	201:11 202:7	308:6 309:17	286:10,15 300:19
129:10 130:10,21	welcoming 9:11	278:10 309:5,21	321:1,4	313:4
131:13,20 134:6	well-run 88:11	310:7 311:3,14	worked 197:1	yeoman's 146:4
137:2,22 138:16	Wendy 2:4 6:4	312:2,9,17 313:18	321:8 324:3	yesterday 199:6
140:2,6 142:5	went 19:10 25:8,14	315:22 317:7	workflows 71:17	yielding 289:2
144:4 162:9	49:6 73:17 74:3	319:18 320:15	working 14:22 16:4	yogurt 37:4 56:19
208:21 240:10,22	76:1 79:3 103:3	322:3	200:22 204:3	136:10 320:7
241:2 242:10,13	104:4 130:17	willing 309:9	240:19 251:5	young 276:21
243:2 244:4,11	153:4 188:10	Winzenberg 298:4	world 11:16 18:15	307:15
245:19 246:9,13	192:11 196:22	Wisconsin 226:20	49:21 63:8 135:4	younger 205:2
246:19 247:13	211:1 221:8	wishes 10:15	181:16 202:1	283:6
248:11,16 249:7,8	236:12 239:12	women 29:22 121:3	269:16	youth 283:22
249:11 250:22	320:6 324:18	148:4,5 192:11	worldwide 10:21	you're 157:9
251:4 253:3,5,6,8	332:8	194:3 201:12	worried 214:14	
253:20 254:2	weren't 86:22	202:8 269:11,15	216:21 321:12	Z
255:4 256:9 257:3	254:10 261:5	271:1 272:12	worry 218:15	zero 60:20 235:6,12
257:5,7,7,17,17	Western 35:17	273:2,8,15 274:9	worthy 138:6	327:14
257:21,22 258:1,4	we'll 71:5,14 74:22	274:13	wouldn't 36:16	Zhan 45:12
258:5,5,7,9,10	168:4 230:18	Women's 40:19	44:6 67:8 86:13	zinc 305:22
				zone 262:21

Z-score 305:2	303:22 329:2	294:4 308:21	23 103:8 208:9	95:14 131:20
<hr/> 0 <hr/>	15-minute 152:21	316:22	239 3:6	216:2
0 279:18	150 241:11	20-year 147:8	24 119:11	500 11:17 150:2
0.2 270:20	16-week 303:21	200 155:20 230:22	25 45:7 76:17 157:1	198:6
0.6 270:19	17 207:2 300:21	232:3,22 233:5	318:4	54 303:21
<hr/> 1 <hr/>	301:1	2000 25:10 130:18	250 172:21 174:11	55 282:21
1,000 231:22	18 42:5 117:6	211:2 221:8	175:16 178:11	<hr/> 6 <hr/>
1-866-239-3239	131:17 147:7	235:18 246:4	185:11 233:17	6 230:5
12:6	246:5 279:18	268:18	237:19	60 79:2 304:7
1.2 272:11	292:12,15	2000-calorie 235:3	259 237:16	600 150:3
1:25 239:11	18-year 292:22	2001 157:11	27 173:8 288:8,10	65 326:1 331:22
10 17:22 103:17,20	18-year-old 289:16	2003 205:22	332:15	332:9
109:14 147:16	18.5 332:14	2004 73:18 132:19	290 232:1	<hr/> 7 <hr/>
158:19,19 163:19	19 99:8 246:5	146:20 158:8,21	296 237:15	7 155:15 156:22
164:1 192:9,18	324:19	163:22 205:21	<hr/> 3 <hr/>	161:2 228:6 229:4
196:22 197:8	19-year-olds	279:16 280:9	3 94:12 189:19	230:6,14
221:7 222:2,16	278:21	282:4 283:2,9	194:10 329:3	70s 254:19 320:6
224:6,8 244:3	1970s 265:2 278:19	285:2,3 290:14,15	3,200 232:1	<hr/> 8 <hr/>
286:9 291:2,3	1972 241:8	295:15 324:18	30 95:14 197:2,5	8 230:4 234:9,14
304:3	1980 303:5	2005 20:15 73:16	275:21 322:7	235:7 289:13
10-year 211:5	1982 285:3 290:15	98:10 100:12	300 178:11 198:5	294:4 301:1
100 124:6	291:19 295:17	112:2 130:11	31 327:2	80 275:6
1000 307:18	298:18	146:16 158:4	34 287:10 332:15	<hr/> 9 <hr/>
11 158:21 160:20	1990 99:7	159:5 176:8	35 318:4 319:8	9 230:4 304:14
291:1,13	1995 332:8	189:12 220:2,3	330:8	329:3
11-year 278:20	<hr/> 2 <hr/>	245:21 248:12,16	36 283:4 327:1	9:00 1:11 4:2 333:2
11:35 153:3	2 26:12 27:9 32:13	249:13 257:19	37 113:4	90 241:8
11:45 152:21	32:15,18 39:2,21	268:14 316:20	38 283:4	900 21:5
11:49 153:6	41:1 73:12 74:18	332:6,8	<hr/> 4 <hr/>	92 231:22
12 234:18 235:2,10	79:15 84:2 146:12	2006 117:22 119:9	4 3:3 104:5 329:3	
278:21 287:2	146:15 147:4	180:17 235:21	4:07 333:9	
288:14 292:15	148:3,19 149:10	286:8	40 216:2 289:15	
300:8,14 305:4	156:9,12,20 159:9	2007 172:3	294:5 317:9 326:1	
327:22 328:21	159:18 160:8,15	2008 72:11,14	400 150:2	
120 79:3	160:17 161:7,19	2009 13:10 103:15	43 104:4	
13 1:10 28:3 271:2	163:3,10 164:16	109:13 146:20	45 281:19	
292:8,22 296:2	165:16 166:1,13	279:16 280:10	45% 328:18	
327:4	170:4 206:11	285:2 288:5	<hr/> 5 <hr/>	
134 266:3	229:9 233:7	290:14 295:16	5 4:14 155:16	
14 103:13 249:20	272:11 289:16	303:6	160:11 161:1	
286:15 304:14	332:3,10	2010 1:10 4:15,19	224:4,7 227:21	
307:18 321:8	2-1/2 147:16	5:14 14:18 25:5	228:12 229:5	
147 241:10	2:15 239:9	250:9 265:14	230:13	
15 160:22 173:9	2:18 239:13	268:18	5.5 230:13	
270:12 281:21	20 18:2 52:19 161:1	21 287:1,14	50 76:3 78:7 83:20	
288:10 299:8	197:2,5,7 289:14	215 304:19		
		22 3:4		