

UNITED STATES OF AMERICA
DEPARTMENT OF AGRICULTURE
AND
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIETARY GUIDELINES ADVISORY COMMITTEE
FOURTH MEETING

THURSDAY, NOVEMBER 5, 2009

The meeting came to order at 8:00 a.m., Dr. Linda Van Horn, Chairperson, presiding.

PRESENT:

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

ALSO PRESENT:

CAROLE DAVIS, MS, RD, CO-EXECUTIVE SECRETARY
AND DFO, CNPP, USDA
KATHRYN McMURRY, MS, CO-EXECUTIVE SECRETARY,
ODPHP, HHS

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ALSO PRESENT (Continued):

SHANTHY BOWMAN, PHD, CO-EXECUTIVE SECRETARY,
ARS, USDA

HOLLY McPEAK, MS, CO-EXECUTIVE SECRETARY,
ODPHP, HHS

RAJ ANAND, DVM, MPH, EXECUTIVE DIRECTOR,
CNPP, USDA

RADM PENELOPE SLADE-SAWYER, PT, MSW, DEPUTY
ASSISTANT SECRETARY FOR HEALTH, DPHD,
HHS

CAPT SARAH LINDE-FEUCHT, MD, Deputy Director,
DPHD, HHS

ROBERT POST, PHD, Deputy Director, CNPP, USDA

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

2 (8:00 a.m.)

3 CHAIRPERSON VAN HORN: Well, good
4 morning, everyone. Welcome to the second day
5 of our meeting of the Dietary Guidelines
6 Advisory Committee. It's a beautiful sunny
7 day here in Washington, and I hope it is nice
8 wherever you are.

9 I'm Linda Van Horn, and I'm the
10 Chair of this committee, and I'm looking
11 forward to having a really robust day filled
12 with lots of comments from the group.

13 Yesterday we heard from the
14 nutrient adequacy and carbohydrates and
15 protein subcommittees. Today we'll also hear
16 updates on the work from the remaining five
17 subcommittees.

18 I'd like to reiterate for everyone
19 that everything being presented today is in
20 draft form, and although as a committee we
21 need to come to agreement on many conclusions,
22 as many as possible, for some topics,

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1 especially those for which there are still
2 puzzle pieces missing or collaborative work
3 between subcommittees planned, additional
4 discussion will be needed after this meeting
5 before the material is finalized.

6 I'd like to remind each committee
7 member to please announce themselves when
8 speaking to help the public follow along as
9 well.

10 And today we're going to kick off
11 with Dr. Larry Appel, who is going to talk
12 about sodium, potassium and water.

13 Larry.

14 MEMBER APPEL: Wonderful. Thank
15 you very much.

16 This is Larry Appel. I'm a member
17 of the Dietary Guidelines Committee.

18 First I want to acknowledge
19 members of the Subcommittee on Sodium,
20 Potassium and Water. Besides myself, Tom
21 Pearson, Christine Williams and our superb
22 staff, Holly, Pat, Donna, and Joan, working

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1 diligently. Every Friday morning, bring your
2 coffee; join us.

3 Okay. So these are the topic
4 areas we are considering in our group, and
5 we've completed reviews and draft conclusions
6 for water, sodium and blood pressure in
7 children, sodium and blood pressure in adults.
8 Ongoing are potassium, dietary patterns, and
9 blood pressure in children and adults which
10 might interface with the nutrient adequacy
11 group. So we need to coordinate there, and
12 sodium-potassium interactions.

13 So we're going to start with
14 water. Keep it easy. To start off with I
15 have my prop, coffee. I see other people with
16 their props, too.

17 So the research question is: what
18 amount of water is recommended for health? And
19 this one, there wasn't a huge amount of
20 literature. We did exploratory literature
21 searches on water and hydration in both adults
22 and children; water and kidney stones where I

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1 think there's strong biologic plausibility as
2 well as some clinical studies, but not really
3 major general population studies; water in
4 bladder cancer; water in body weight, and we
5 identified no major study published since the
6 last dietary guidelines that covered these
7 topics that would affect our recommendations.

8 And we also queried one of the
9 leading experts in the field who participated
10 in one of our calls, Mike Sawka. That was his
11 impression as well. So we also drafted our
12 statement.

13 So this is what our draft
14 conclusion is. I think we have some
15 wordsmithing to do, but our draft conclusion
16 is consumption of water is necessary to
17 maintain health. However, there is no
18 evidence of dehydration or other problems
19 relating to inadequate water intake in the
20 general population.

21 We're struggling with the grading
22 issue that everybody else is. So I won't put

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1 a grade here for now, in part, because the
2 basis for this is the Institute of Medicine
3 report and then we supplemented it with the
4 last four or five years of literature for
5 which there's very little.

6 So there are implications of this,
7 and much of this is actually drawn explicitly
8 from 2005, but we also add some. So the first
9 of the combination of thirst and usual
10 drinking behavior, especially the consumption
11 of fluids with meals, is sufficient to
12 maintain normal hydration.

13 Second, healthy individuals who
14 have routine access to fluids and who are not
15 exposed to heat stress consume adequate water
16 to meet their needs.

17 Third, purposeful drinking is
18 warranted for individuals who are exposed to
19 heat stress or who perform sustained vigorous
20 activity.

21 And then these are two new
22 implications. No quantitative recommendation

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1 for minimum water consumption can or should be
2 set. In view of the obesity epidemic,
3 individuals should select water or fluids with
4 few or no calories.

5 So it might be worthwhile stopping
6 here because the next section is sodium, and
7 this is a diversion. Yes.

8 MEMBER PI-SUNYER: Larry, a lot of
9 people -- this is Xavier -- a lot of people
10 think that drinking a lot of water will reduce
11 the amount of food they eat and defend against
12 obesity, and as far as I know the literature
13 doesn't show anything to that regard. Do you
14 think something should be put in here about
15 that?

16 It's kind of a negative, but --

17 MEMBER APPEL: Yeah, that was sort
18 of subsumed under the weight, relationship of
19 weight or of water intake and weight. We
20 could, but the problems that would come would
21 be counter to that last one, which is where we
22 want to -- I mean, I do think even if we might

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1 not have perfect evidence for each source of
2 calories and weight, we probably want to, you
3 know, as a theme encourage lower calorie foods
4 and beverages.

5 So the problem if we were to say
6 there's no evidence of or if there's a
7 creative way of saying what you want without
8 negating that last one, I think we could do
9 it, yeah.

10 Yes.

11 CHAIRPERSON VAN HORN: The other
12 thing that our group talked about because, of
13 course, of the obesity epidemic and water,
14 having no calories as being an ideal fluid
15 source; the other problem and something that
16 we'd want to recommend, I think, for the
17 future is just the whole assessment issue
18 because so many studies really fail to
19 adequately document water intake, and so the
20 opportunity may not necessarily be that there
21 are no data or, I mean, that there is no
22 relationship. It's just that the data we

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1 currently have is missing the accuracy that we
2 need in order to make that comparison.

3 MEMBER APPEL: Yes. Your point is
4 well taken. I mean, we rely on NHANES, and
5 that's self-reporting and wasn't our primary
6 focus.

7 On the other hand, the data about
8 hydration actually is probably less amenable
9 to the kind of traditional studies that we
10 think about. When we reviewed the literature
11 for the Institute of Medicine, one of the more
12 fascinating things was that serum osmolality,
13 which is the major bioindicator of hydration
14 status, is rock solid, you know, whether
15 you're consuming very little water or a lot.

16 So even if you have a lot of
17 misclassifications, you know, you see the same
18 thing. You know, people within an age
19 stratum, it really makes no difference, a
20 little or a lot water. Their serum osmolality
21 is the same.

22 So there's really no evidence of

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1 at least the medical problem of hydration. The
2 issue that I think you raised is sort of the
3 chronic disease relationships for which you do
4 want to have, you know, better exposure data,
5 and so at this point it's not a great exposure
6 to measure.

7 MEMBER SLAVIN: I have a question
8 about the liquids and solids because it does
9 overlap with our committee, too. So I guess I
10 want to make sure -- it's Joanne Slavin here
11 -- that we talk about that.

12 I agree with Dr. Pi-Sunyer though
13 that the water intake and calories, people
14 think that, but there's no data at all, and in
15 animals it's actually the opposite, that
16 access to water, you know, they take in more
17 calories. So I don't know how to make -- you
18 know, just not to mislead people to think by
19 drinking water it's going to help them in
20 calorie balance.

21 You know, the calorie idea makes
22 sense because it's calorie free, but there's

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1 no real data to support that it's going to
2 help in weight maintenance.

3 And the other question for our
4 committee with increases in fiber, that also
5 overlaps with the fluid committee. So making
6 sure we do some cross-talk on that if there's
7 suggestions for higher fiber intakes.

8 MEMBER APPEL: Okay. Great. So
9 let's proceed ahead to the next topic.

10 So we're going to talk about
11 sodium and salt sodium chloride. Actually
12 this is going to be a little bit of a
13 different presentation compared to some of the
14 others. We will cover, you know, conclusions,
15 implications, but I think the background is
16 important in this. So there will be a more
17 contextual type of presentation in addition to
18 the usual.

19 So these are the way that sodium
20 data is presented, which is confusing because
21 you have sodium in milligrams, which is on the
22 back of the nutrition facts panel, and then

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1 you have sodium in millimoles, which is what
2 we measure when we do collect 24-hour urines,
3 and then sodium chloride. Actually in Europe
4 all of the recommendations are based on sodium
5 chloride salt.

6 So I'm going to actually, to the
7 extent possible, discuss sodium in milligrams,
8 and the Institute of Medicine reports that a
9 upper limit of 2,300 milligrams and an
10 adequate intake level at 1,500 milligrams
11 though, you'll see those numbers in this
12 presentation repeatedly.

13 So in terms of adverse effects of
14 sodium, there is an established relationship.
15 You're not going to get the Salt Institute now
16 to debate this one, that there is a
17 relationship between salt intake and blood
18 pressure, and there is a strong relationship
19 between blood pressure and cardiovascular
20 disease, coronary heart disease, and stroke.

21 This is based on largely
22 pharmacologic -- well, there's a risk

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1 relationship that's very robust, and I'll show
2 you data on that. There's also strong
3 evidence that a variety of different
4 medications that lower blood pressure also
5 prevent cardiovascular disease and stroke. So
6 it is the perfect biomarker, and it's one of
7 the few biomarkers that we actually have. We
8 don't obviously have one for cancer, but it is
9 a great one for cardiovascular disease, along
10 with LDL cholesterol.

11 There are other relationships, and
12 there's a probable relationship of sodium
13 intake with gastric cancer, and I'm not going
14 to cover that, and then suggestive
15 relationship of sodium with osteoporosis, left
16 ventricular mass, and then a hypothesized
17 relationship with obesity.

18 Now, in terms of the blood
19 pressure problem from a population
20 perspective, cardiovascular disease, the
21 combination of coronary heart disease and
22 stroke is the leading cause of death in the

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1 United States. Coronary heart disease is the
2 first and stroke is the third leading cause of
3 death, and it has been estimated that 62
4 percent of strokes and 49 percent of coronary
5 heart disease events are attributed to
6 elevated blood pressure.

7 And this is not just those that
8 are above the limit called hypertension. It's
9 above what we call normal or optimal blood
10 pressure, depending on how you define it. But
11 if you do use the clinical classification of
12 hypertension, which I'll review, about a
13 quarter of the population, adults, has it. So
14 it's a huge public health problem.

15 From an individual perspective,
16 lower the blood pressure, lower your risk of
17 heart disease even if you don't have
18 hypertension. And the lifetime risk based on
19 data from Framingham is that you'll develop
20 hypertension. It's almost inevitable. If you
21 reach the age of 50 you'll get it.

22 So this is the classification. We

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1 consider normal less than 120/80, and then
2 pre-hypertension an intermediate category, and
3 then hypertension a higher category. This is
4 a pie diagram from several years ago. About
5 just under a third of the population has
6 hypertension, a third with pre-hypertension,
7 and about 40 percent normal.

8 Trends are actually going in the
9 bad direction with increasing blood pressure
10 levels, and I'll show you some data on that.
11 So people did not listen to the 2005
12 guidelines. You know, that's the problem.

13 (Laughter.)

14 MEMBER APPEL: You know, otherwise
15 we would be okay, all right.

16 So the problem with high blood
17 pressure though is not just the absolute
18 levels, but it's this pattern of rise over
19 time, as we age, with about a .6 millimeter
20 rise in mercury per year, which Christine will
21 go over, but also there's an adverse pattern
22 in children. So the pattern of elevated blood

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1 pressure and the clinical manifestations in
2 adulthood really is a childhood problem. It's
3 almost like osteoporosis in the sense that
4 it's a condition that reflects a lifelong
5 process.

6 So here's data in older age, but
7 the same is true in other age groups, that the
8 blood pressure problem, in this case defined
9 by prevalence of hypertension, is getting
10 worse, and this is in older age individuals,
11 and it occurs whether you're white or black or
12 Hispanic. Okay. So this is the risk
13 relationship.

14 So is, in part or in large part,
15 why the recommendations extend to the whole
16 population, because whether your blood
17 pressure is, you know, 140, 130, it's always
18 better to be a bit lower. Okay? And each of
19 those curves represents an age epic.

20 I'm on that lower one, the 50-59.
21 That one just goes like that, you know, and
22 that is the line that divides hypertension. So

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1 if you're to the left of that line, you still
2 have that progressive risk relationship. The
3 people to the left of the line would not be
4 treated with medication. You go in a doctor's
5 office with that level, you don't get
6 medication. They'll just say, you know, lose
7 weight, eat a healthy diet, reduce your sodium
8 intake, but that's where it has been estimated
9 about a third of coronary heart disease events
10 occur in that range.

11 So the rationale for reducing
12 blood pressure is, in part, displayed in the
13 last slide, but here's the distribution of
14 blood pressure. If you start with a Gaussian
15 distribution of blood pressure that shifted to
16 the left, you're going to get benefits. The
17 benefits accrue from relatively small
18 reductions in blood pressure.

19 So in that table at the bottom,
20 relatively small reductions in blood pressures
21 lead to very large actually estimated
22 reductions in mortality, and it's very

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1 interesting because even my colleagues who are
2 more sort of clinical hypertension people
3 really buy into this now because they've seen
4 some of their clinical trials screwed up
5 because of small differentials in blood
6 pressure that seem to account for, you know,
7 perplexing findings.

8 So this is likely real and
9 accepted broadly by the public health and
10 clinical communities.

11 So with that as background, we're
12 going to go to sodium blood pressure in
13 children, and Christine is going to take
14 charge here.

15 MEMBER WILLIAMS: Thank you,
16 Larry.

17 Christine Williams.

18 This is the pediatric side of the
19 sodium and blood pressure question, and the
20 question is: what is the effect of sodium
21 intake on blood pressure in children from
22 birth to 18 years?

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1 In the United States and most
2 other countries, blood pressure slowly rises
3 with age, and most children whose blood
4 pressure appears to be in the healthy range
5 during childhood are still at eventual risk of
6 hypertension as adults. Blood pressure during
7 childhood exhibits significant tracking
8 phenomena.

9 Mean blood pressure levels have
10 increased among U.S. children and adolescents
11 over the past two decades. Higher blood
12 pressure in childhood increases the risk of
13 cardiovascular disease in adult life and is
14 also associated with cardiovascular
15 abnormalities in youth as well, for example,
16 left ventricular hypertrophy.

17 High blood pressure, as well as
18 other cardiovascular disease risk factors in
19 youth is associated with the presence of early
20 atherosclerotic lesions.

21 Some of the increase in mean blood
22 pressure in U.S. children can certainly be

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1 attributed to increasing rates of childhood
2 obesity, which have tripled and quadrupled
3 over the past two decades. Other factors,
4 including dietary intake of sodium and
5 potassium, also increase blood pressure levels
6 in children.

7 Dietary intake of sodium in U.S.
8 youth is currently at unacceptably high
9 levels, with the majority of children and
10 adolescents exceeding the upper level of
11 recommended intake. Diets rich in potassium
12 can lower blood pressure. However, dietary
13 intake of potassium among U.S. youth is very
14 low, with less than three percent meeting
15 recommended levels.

16 So the rationale for conducting a
17 review of the evidence for this research
18 question was that the mean blood pressure
19 levels and prevalence of hypertension and pre-
20 hypertension in children are increasing. Thus,
21 there's some urgency to provide public
22 guidance and promote interventions that are

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1 likely to retard and reverse this unhealthy
2 trend.

3 There's evidence that blood
4 pressure elevations in children and
5 adolescents are not benign, but are associated
6 with immediate and future adverse effects on
7 the heart and the vascular system.

8 And there's evidence that dietary
9 sodium influences blood pressure in childhood
10 similar to the effect observed for adults.
11 Here you can see the annual increase in blood
12 pressure for children, the systolic blood
13 pressure. The increase is 1.9 millimeters of
14 mercury per year for boys and 1.5 millimeters
15 of mercury for girls. And this is actually
16 significantly greater than the increase that
17 you see for adults.

18 This is the comparison of blood
19 pressure levels for children from NHANES III,
20 1988 to '94, and NHANES '99 to 2000, and you
21 can see the increase in boys and girls similar
22 to what we are seeing in adults.

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1 Blood pressure in adolescents is
2 associated with subsequent cardiovascular
3 disease. There are a number of studies that
4 have reported this. There are autopsies --

5 (Pause in proceedings for
6 technical difficulties.)

7 MEMBER WILLIAMS: Blood pressure
8 measured in adolescents and young adults is
9 associated with subsequent cardiovascular
10 disease. Autopsy studies have shown that
11 there are fatty streaks that begin very early
12 in life and eventually progress to more
13 complicated lesions, and then observational
14 studies have shown that coronary artery
15 calcification and eventual cardiovascular
16 events are also associated with blood pressure
17 in adolescents. These have been reported by
18 the PDAY study, CARDIA, Muscatine, and other
19 studies.

20 So we conducted a review of sodium
21 intake and blood pressure in children, and we
22 extended our search back to January of 1970,

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1 and this included all healthy children between
2 the ages of birth and 18 years of age, peer
3 reviewed articles that were conducted in the
4 United States or internationally in the
5 English language, and we included only
6 randomized controlled trials or clinical
7 controlled trials and prospective cohort
8 studies, systematic reviews or meta-analyses,
9 sample size at least ten per study group and
10 less than 20 percent dropout rate.

11 We found 19 studies that were
12 included in the final review, 15 clinical
13 trials, 14 randomized controlled trials, and
14 14 prospective cohort studies. Of the 19
15 studies, eight of them were in the positive
16 quality rating, and eight were rated neutral;
17 three rated negative.

18 The studies ranged in sample size
19 from 21 to almost 1,000. Nine of the studies
20 were conducted in the United States. Six were
21 conducted in Australia, three in the
22 Netherlands, two in U.K., and one study each

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1 in Israel and South Africa.

2 And the included studies were
3 published between -- I'm sorry. I can't see
4 that last part there -- okay. Eighty-one in
5 2008. The 19 studies were included in the
6 final review, 15 clinical trials and 14
7 randomized controlled clinical trials, and
8 four prospective cohort studies. Ten of the
9 15 clinical trials achieved contrast in sodium
10 intake of 40 percent or more between the
11 treatment groups or periods. Of the 15
12 clinical trials, 12 reported a decrease in
13 systolic and/or diastolic blood pressure on
14 the lower sodium diet. In eight of the 12
15 studies the decrease was statistically
16 significant. Three trials reported no change
17 in blood pressure on a low sodium diet.

18 (Pause in proceedings.)

19 MEMBER WILLIAMS: And four
20 prospective cohort studies were included in
21 final review. Three of the studies, two
22 positive, one neutral, found evidence that

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1 lower sodium intake was associated with lower
2 blood pressure. A study of 533 infants
3 followed seven years; another study of 233
4 children followed seven years; and a final
5 study which was a 15-year follow-up of infant
6 randomized controlled trials where systolic
7 and diastolic blood pressure at the 15-year
8 follow-up was still lower among the children
9 who were initially assigned to the low sodium
10 diet during infancy.

11 And one study found a positive
12 linear relationship between infant blood
13 pressure one year and a rough estimate of
14 quantity of salt added to the infant's diet
15 during the previous year.

16 We also used a meta-analysis as
17 background material. All of the ten trials
18 included in this meta-analysis were
19 individually reviewed by us in our review, but
20 you can see from systolic changes in the
21 diastolic that the majority showed small but
22 significant decreases in blood pressure for

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1 both systolic and diastolic.

2 So in summary, a review of the
3 evidence indicates that sodium reduction
4 modestly lowers blood pressure in children
5 from birth to 18. The degree of blood
6 pressure lowering was usually small, in the
7 range of minus one to minus five millimeters
8 of mercury.

9 However, such an effect if
10 sustained over time could translate into
11 reduced blood pressure in adults, as well as
12 reduced prevalence of hypertension.

13 Furthermore, if a reduced sodium
14 intake blunts the age related rise in blood
15 pressure in children, then the effects of
16 sodium reduction will be greater than
17 projected for these studies. It must be
18 acknowledged, however, that most of the
19 studies had methodological limitations, small
20 sample size, and consequently inadequate
21 statistical power, brief duration, typically
22 less than a month, and inadequate or uncertain

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1 contrast in sodium intake.

2 So, in summary, our draft
3 conclusion is that a lower sodium intake
4 appears to reduce blood pressure in children
5 from birth to 18 years, with a Grade 2, and
6 implications among children adolescents a
7 lower sodium intake likely has beneficial
8 effects on blood pressure, and a reduced blood
9 pressure early in life should translate in to
10 health benefits later in life, delaying and
11 potentially preventing the consequences of
12 chronically elevated blood pressure.

13 I'd be happy to take any
14 questions.

15 MEMBER APPEL: This is Larry
16 Appel.

17 Can we take the questions at the
18 end? Because there's a lot of material that's
19 all related to sodium, and there's also some
20 contextual material that I think is relevant
21 and might obviate some questions.

22 Okay. So this is Larry Appel

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1 again.

2 The second question that we
3 addressed in detail was what is the effect of
4 sodium intake on blood pressure in adults, and
5 it's important to point out that we do have a
6 substantial evidence base, not only there is
7 actually I think it's 2005 Institute of
8 Medicine report, but also there have been, you
9 know, authoritative bodies in meta-analyses on
10 this topic, over 50 trials with sodium
11 reduction on blood pressure; ten dose response
12 trials; and three trials in sodium reduction
13 as a means to prevent hypertension.

14 Chris mentioned methodologic
15 limitations. You also have these with this
16 group of studies to particularly the trials,
17 and one thing that wasn't mentioned and I'll
18 deal with is the measurement of blood pressure
19 which was often suboptimal in a lot of
20 studies.

21 And because there is so much
22 within person variability, you have to have a

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1 lot of measurements, high quality measurements
2 in order to detect change. So that was also
3 an issue with the children's study.

4 So anyway, Christine's search went
5 back 30 years. We just went back to June
6 2004. The question at hand was the
7 relationship of taking blood pressure in
8 adults. We focused on healthy adults. Those
9 with chronic disease risk, those with
10 diagnosed or highly prevalent conditions, 19
11 years of age or older, peer reviewed U.S.
12 English language.

13 This field, you know, we're not
14 going to use cross-sectional data because we
15 have enough experimental studies. So it was
16 just clinical trials or prospective cohort
17 studies, systematic reviews or meta-analyses,
18 and we have to have at least ten in each study
19 and less than 20 percent dropout.

20 So there were even after the
21 report or after 2004 there were 13 studies, 12
22 clinical trials. Actually we call them

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1 clinical trials, but nine of them were
2 randomized clinical trials. Two had tested
3 different levels of sodium intake, but the
4 order was fixed, but not randomized, and then
5 one observational study, the previous trial,
6 and one systematic review.

7 I want to point out that this is
8 fairly settled science. So the reason that
9 these studies were done was often for another
10 reason, like you know, what is the effect of
11 sodium on proteinuria or the effect of sodium
12 on, let's say, pulse wave velocity, some other
13 biovariable.

14 And, by the way, they also
15 presented blood pressure because that's really
16 you want to get funded to do something for
17 which there's overwhelming evidence.

18 So of the 13 studies, nine were
19 rated with a positive quality; four were
20 neutral. Sample size ranged from 12 to 2,400.
21 The latter was a genetic study, and the
22 populations were actually often meant to be

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1 demographically heterogeneous. For example, a
2 trial in Great Britain included blacks,
3 whites, and Asian hypertensives, and the
4 studies were created or done throughout the
5 world. In fact, some of these were done as
6 sort of effectiveness types of studies. So
7 they're not really the optimum studies for
8 saying is sodium related to blood pressure,
9 but is this intervention feasible and does it
10 get a result if implemented in Africa. So it
11 was that kind of study.

12 So of the 12 clinical trials, nine
13 reported a statistically significant decrease
14 in systolic blood pressure on a lower sodium
15 intervention. Six reported a statistically
16 significant decrease in diastolic blood
17 pressure, and there was a systematic review
18 from the 34 trials and documented
19 statistically significant reductions of both
20 systolic and diastolic blood pressure on the
21 lower sodium interventions.

22 So in aggregate, these studies

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1 reinforce the previous consultation from the
2 dietary guidelines that a lower sodium intake
3 reduces blood pressure.

4 So our draft 2010 conclusion is
5 the relationship between salt, sodium chloride
6 intake and blood pressure is to direct and
7 progress without an apparent threshold. That's
8 Grade 1.

9 And these are the implications,
10 and I'm assuming that we're going to follow
11 this strategy of conclusions followed by
12 implications. So I'll just go over these one
13 by one.

14 Individuals should reduce their
15 salt intake as much as possible. A daily
16 sodium intake of less than 2,300 milligrams
17 has been recommended for the general adult
18 population, and an intake of 1,500 milligrams
19 for hypertensive individuals, blacks, and
20 middle and older aged adults.

21 Because the latter groups together
22 comprise 69 percent of U.S. adults, the goal

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1 should be 1,500 milligrams. The 69 percent
2 figure was recently published in MMWR and is
3 based on an NHANES analysis.

4 The third point, very important,
5 nonetheless given the current food supply, it
6 will be difficult to achieve a mean intake of
7 2,300 milligrams, much less a lower goal of
8 1,500 milligrams. For this reason, the goal
9 should be incrementally reduced from 2,300 to
10 1,500 milligrams per day.

11 I think that actually reflects a
12 lot of the discussion in 2005, you know, the
13 big feasibility issues that have to be dealt
14 with. This is not an immediate fix, it can't
15 be done easily or immediately.

16 And then individuals, finally,
17 should concurrently increase their consumption
18 of potassium rich foods because a diet rich in
19 potassium blunts the effects of sodium on
20 blood pressure.

21 I prefer to go through all of
22 these and then circle back. I know that

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1 there's going to be discussion. So we
2 actually have spent a lot of time on the
3 contextual issues because the central question
4 of sodium and blood pressure is basically
5 settled science.

6 So the first is other
7 recommendations, then current sodium intake
8 levels, projected health benefits, whether or
9 not to calorie adjust recommendation, review
10 the public comments, salt sensitivity as a
11 concept because it comes up repeatedly, other
12 dietary factors that reduce blood pressure,
13 food sources of sodium, and adverse trends in
14 the food supply.

15 So in 2005, the U.S. dietary
16 guidelines recommended 2,300 milligrams as the
17 upper limit for the general population and
18 1,500 for hypertensive blacks and adults.
19 International groups, actually they're really
20 numerous and pretty consistent in terms of
21 recommending sodium reduction, even though the
22 specific number varied.

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1 So world health organization, less
2 than 2,000. Recently Canada recommended 1,000
3 milligrams for children one to three and for
4 adults 1,500 milligrams.

5 Now, these are actually data that
6 I compiled into a figure that display average
7 sodium intake in males and females by age, and
8 if you look at the left, and those are
9 children age two and three, they're already
10 close to the adult upper limit of 2,300.

11 I didn't put down the recommended
12 limits for children, but they're below 2,300,
13 and as you get older, your consumption of
14 sodium increases and then strikingly increases
15 in adolescents and stays high in middle age
16 and then goes down. And of course, it's
17 higher in men than in women, and in large part
18 that reflects a calorie issue, okay, and this
19 is an important issue, and we'll circle back
20 on that because it gets at an issue. We have
21 an absolute level that we're recommending, but
22 the realities of how we eat, you know, we eat

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1 more calories so that we can get more sodium.
2 So what should we do.

3 Okay, and by the way, the source
4 of these data and some other data I'm going to
5 show is some analysts from NCI that were very
6 helpful in documenting both the amount and
7 food sources of sodium.

8 So there actually have been a lot
9 of studies, some quite recent including this
10 one that have estimated the benefits of
11 reducing sodium from current levels. So this
12 was a study by Palar's American Journal of
13 Health promotion published just two months
14 ago, and it just projected what would happen
15 if you decreased sodium from the current
16 levels down to the upper limit of 2,300 and
17 down to 1,500. So you can see the changes in
18 blood pressure, the percent of adults who are
19 hypertensive, reduction in hypertension,
20 direct health care costs saved and annual
21 quality of life saved, as well. So these are
22 benefits that are substantial.

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1 And actually it's interesting.
2 There are more of these that are coming out,
3 you know, that are reaching, you know, roughly
4 the same conclusion. Often different sets of
5 outcomes, but there are health and economic
6 benefits.

7 This was actually an analysis, I
8 think from Eric's group where there were the
9 effects of various things that we're actually
10 considering on mortality modifiable life style
11 or modified risk factor and lifestyle habits.
12 Smoking is still at the top, right, you know,
13 and this is the estimated number of deaths
14 that could be averted if you just brought
15 everybody down to sort of an optimal
16 condition. So the top one is smoking, going
17 from smoking to no smoking in the whole
18 population. So it has been estimated around
19 450,000.

20 So the next one is high blood
21 pressure, and that is basically treatment of
22 high blood pressure and getting everybody down

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1 to recommended levels, and the obesity,
2 physical activity, glucose, cholesterol and
3 salt, 102,000 deaths prevented. If you got
4 down -- I think the level of use was 2,300,
5 not the 1,500.

6 So other issues. Should
7 recommendations for sodium and potassium be
8 calorie adjusted? And we had a very -- we
9 brought this up at the last meeting, but then
10 we also had a conference call with Shiriki
11 Kumanyika, Cheryl Anderson and Nancy Cook to
12 discuss this issue, the scientific rationale,
13 if there is one.

14 And the reason it's calorie
15 adjusted is that, as I said, absolute intakes
16 of sodium as well as potassium are
17 inextricably linked to calorie intake. The
18 higher the calorie intake the higher the
19 sodium and potassium.

20 In real life we adjust by
21 calories. You know, you eat at a table. You
22 eat more, you know, if you're an athlete like

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1 Mim and you run a lot. You probably are
2 consuming 3,000 calories. You're going to get
3 more of a salt load and, you know, a slug like
4 Eric who sits around.

5 (Laughter.)

6 MEMBER APPEL: -- you know,
7 basically just shows up and drinks alcohol.
8 You can subtract that from the minutes. We're
9 friends. We're friends. I can say that.

10 But in real life, you know, when
11 you do clinical trials actually, we actually
12 adjust. So even in the DASH sodium trial that
13 had lower intermediate and higher levels of
14 sodium, those levels differed by the amount of
15 calories you consumed. Okay? So I'll show
16 you that in a second.

17 So the reasons just really deal
18 with practical reasons, but there is no
19 biologic reason. If you need very little
20 salt, you know, you don't adjust upward
21 something where you're already in excess of
22 that limit. So it's a conflict between the

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1 science which would say you don't need to
2 adjust, but the practical reality which is
3 that you do adjust, you know, and it would be
4 almost impossible to think of a way to
5 separate people would have to be eating
6 different food at the same table, and it just
7 doesn't make sense.

8 So anyway, this is what we did in
9 one of our clinical trials. There's a sodium
10 trial, and this shows you the issue. So if
11 somebody was consuming 1,600 Kcals to maintain
12 their weight, our lowest level of sodium that
13 we provided was 40, but if you're consuming
14 3,100 Kcals, that's the lowest row. The
15 intake would be 70.

16 So okay. So we also considered
17 public comments. We got a stack of comments.
18 Still going through those. So you get
19 recommendations from both sides saying we
20 should be more restrictive, should be less
21 restrictive. So others recommended a very
22 general population guideline, adding guideline

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1 for children, updating our methodology similar
2 to what we're doing now; consider savings and
3 linking it to clinical outcomes.

4 Others suggested or concomitantly
5 recommended focus on dietary patterns rather
6 than sodium intake, proving diet quality is
7 the primary strategy for blood pressure, and
8 recommending more emphasis on potassium.

9 There are just a lot of comments,
10 and we are reading those and considering
11 those, and actually they provide some useful
12 references as well.

13 So salt sensitivity is a concept
14 that we constantly hear about, and I think
15 this is also relevant to other groups,
16 particularly the lipids group where it
17 basically is inter-individual variability,
18 inter-individual variability and
19 responsiveness. And this is very common for
20 biological variables.

21 The problem with sodium is that
22 there's huge inter-individual variability with

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1 blood pressure, just a measurement itself,
2 well, both a measurement and biologic
3 variability that makes it very difficult to
4 label any individual as saltensive.

5 It's very interesting as a
6 biologic concept, but it's not really relevant
7 as a public health concept, given the massive
8 scope of the epidemic. So there are these
9 factors that are associated with salts
10 sensitivity and led to the lower level being
11 recommended of 1,500 milligrams for many
12 people in these groups, African Americans,
13 middle and older age individuals, and
14 individuals with hypertension, but they're
15 also modifiable.

16 And we acknowledge this. You
17 know, people have said that, well, you know,
18 you should be really emphasizing a high
19 quality diet or a diet high in potassium, but
20 you know, we actually are recommending both.
21 It's not either/or, and the reality is that
22 most people, you know, make partial changes,

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1 not go full force, don't meet necessarily just
2 one recommendation.

3 So in terms of some groups there
4 is convincing evidence African Americans have
5 a greater blood pressure reduction compared to
6 non-African Americans, but both groups do
7 achieve benefit, and these are data from the
8 DASH sodium trial.

9 So as I mentioned, it is possible
10 to identify groups that have greater response
11 to sodium reduction, but there's tremendous
12 variability within group, and it is impossible
13 to identify salt sensitive individuals, and
14 it's really irrelevant as a public health
15 concept, given the vast scope of the blood
16 pressure and cardiovascular disease epidemics.

17 I'm not going to go over these
18 slides. I want to make sure we have enough
19 discussion. There are other dietary therapies
20 that have been recommended to reduce blood
21 pressure: weight loss, increased potassium
22 intake, dietary patterns, and alcohol.

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1 And the bottom line is that you
2 get benefits. This is a combination of a good
3 diet and sodium reduction, and you get better
4 effects if you combine both, you know, and
5 likely if you recommended an individual to
6 improve their diet and reduce their sodium,
7 they would go part way down both rather than
8 meeting just one or the other. So what we're
9 doing with dietary guidelines, I think, is
10 right, which is to recommend as many of the
11 things that we think are beneficial.

12 So sodium sources. We have a big
13 problem in that our food supply is replete. We
14 did do some research and the NCI people did a
15 lot of analyses to identify sources and
16 identify 12 food groups that each supply over
17 100 milligrams on average per day per person
18 to the diet and that collectively provide
19 about 56 percent. So it's not surprising that
20 these are yeast breads, chicken and chicken
21 mixed dishes, pizza, pasta and pasta dishes,
22 cold cuts, condiments, Mexican mixed dishes,

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1 sausage, franks, bacon, cheese, desserts,
2 grain based desserts, soups and beef and beef
3 dishes.

4 Now, I'll end with adverse trends
5 in the food supply. There are many
6 manufacturers that are already reducing their
7 sodium, and in fact, there have been -- I
8 won't mention companies -- there have been
9 several that have been very prominent in we're
10 going to reduce our sodium by 20 percent.

11 The problem is that it's not
12 occurring uniformly in all of those groups,
13 and further, there are certain categories of
14 foods where we think that there's a problem,
15 and it's really below the surface, and the
16 public isn't aware of it. We're not even sure
17 nutritionists are even aware of it.

18 And so we have no systematic way
19 of understanding this. This is trying to
20 define and identify issues. The two areas
21 that we did find were that transition foods in
22 infants, and these are just some examples of

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1 foods. I didn't label the food explicitly,
2 but it's the potato-cheese product that's used
3 as infants through a transition period to
4 solid foods, provides 100 calories, 310
5 milligrams of sodium. So sodium density is
6 like 2.8, which in most foods even for adults
7 are around two or a little bit less.

8 In a pasta dish that provided 630
9 milligrams, and then in a meat pasta dish that
10 provided 992, and these are fed to children.

11 The other area that is of concern
12 are what we call sodium augmented meats, or
13 the other term is "enhanced meats," and this
14 is something that I think many people are
15 aware of individually, is that you go to the
16 supermarket and the products are injected with
17 sodium solutions.

18 In pork, the ARS has estimated
19 that about 45 percent of raw pork products
20 were augmented with sodium products. This is
21 before they're cooked, and we have a similar
22 problem with chicken, and it seems to be

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1 different, interestingly, by types of stores,
2 where you get less of this occurring in
3 traditional stores but more of it occurring in
4 sort of the large clubs or big box type
5 stores.

6 We don't have great data on this.
7 We have some data on pork, some on children
8 from the manufacturers, but it's even not in
9 the databases from what we understand, which
10 is a big problem. And this points out the
11 problems with NHANES is that, you know, unless
12 you have an up to date database, you know, you
13 could be missing something big like this. So
14 what I presented earlier may not include this.

15 And these are just examples of
16 what's going on. So for chicken, pork, turkey
17 breast, going from natural to augmented, we
18 get huge increases in sodium in products that
19 people had, you know, thought that were, you
20 know, basically sodium free or minimal sodium.

21 So there is modeling that we're
22 going to do to help us with our deliberations.

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1 I'm not going to go into a lot of detail on
2 this. So the current models are based on the
3 most nutrient dense versions, most of which
4 are low in sodium, but you can think of that
5 as sort of intermediate. You could have, as
6 we said yesterday, sort of your typical food
7 choices, which are going to be higher, and
8 then your best available, which is to replace
9 some of those with foods that are lower in
10 sodium.

11 So our next steps are dietary
12 patterns in blood pressure in children,
13 adults, potassium, sodium-potassium
14 interaction, and food modeling, and I think
15 that's it.

16 CHAIRPERSON VAN HORN: Well, thank
17 you, Larry. That was outstanding and
18 certainly a lot of information, and I'm sure
19 that the committee will want to discuss many
20 of those issues.

21 I would like to just jump in by
22 saying that I'm especially excited to see the

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1 new data being presented on children, and
2 especially birth to 18. This will be a new
3 feature of this particular set of guidelines.
4 For the first time it will be talking about
5 children at that age group.

6 We recognize that in the past
7 there haven't been data available for that age
8 group, and now that there are and hopefully
9 will continue to be, I think it's especially
10 important in light of primary prevention that
11 we consider looking at children and diets of
12 children. I think some of the comments that
13 you just made about transition foods aimed at
14 toddlers, for example, that are as high as 900
15 milligrams per serving at that age group is
16 very disturbing, and it's something that I
17 think we are going to need to address and
18 hopefully partner with the food industry in
19 recognizing that, as I was just reminded, that
20 generally people, including children, are
21 eating well above the 2,300 milligrams of
22 sodium that has been recommended.

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1 So the idea of ratcheting down
2 over time seems like a perfectly achievable
3 goal and something that I think we as a
4 country really need to embrace and work on for
5 everyone's health and benefit.

6 So with that, I guess I would just
7 like to open. Xavier, why don't you go?

8 MEMBER PI-SUNYER: Yes. I have
9 two comments for Christine.

10 In your draft conclusion, you end
11 up by saying among children and adolescents a
12 lower sodium intake likely has beneficial
13 effects on blood pressure. Do you think you
14 need the "likely"?

15 MEMBER WILLIAMS: No, I think we
16 could take that out.

17 (Laughter.)

18 MEMBER WILLIAMS: I think the
19 evidence was fairly consistent and moderately
20 strong.

21 MEMBER PI-SUNYER: And the other
22 comment I have is do you think that it would

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1 be good there to take the opportunity -- I
2 know Larry mentions it later -- to talk about
3 the calorie effect? I mean the fact that
4 these children, so many children in the U.S.
5 are overweight to begin with and obese, and if
6 they cut back calories, they'll also cut back
7 sodium, and put something to that effect in
8 the childhood part of this.

9 MEMBER WILLIAMS: Well, I think
10 there's no doubt that a part of the increase
11 in blood pressure is due to the obesity
12 epidemic, but I think that a combination of
13 those interventions would be appropriate and
14 achieve even a greater effect in blood
15 pressure lowering and reducing the increase
16 over time.

17 MEMBER PEARSON: This is Tom
18 Pearson.

19 Larry, we talked about this in the
20 group, and I wanted to raise this calorie
21 adjustment issue, and just speaking for the
22 fatty acid and cholesterol group, it's an

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1 issue for us as well, and I just wonder how
2 many other subcommittees it's an issue.

3 And I don't know if this is a
4 venue to do that or a broader one, but
5 obviously we've been kind of schizophrenic
6 with percent of calories from one nutrient or
7 whatever, and then in the cholesterol area, so
8 many milligrams per day. So we have the same
9 issue, and the data are always totally
10 uninterpretable because of the base amount of
11 caloric intake varies.

12 So as I'll show you later, the men
13 are above the goal and women are below the
14 goal, and it totally has to do with the amount
15 of calories taken in. So I think going
16 forward as a way we can all speak the same
17 language, I very much liked your Kcal level,
18 you know, the kind of model diets.

19 You know, this is not rocket
20 science where you have to get down to the
21 hundredths decimal point, but it's something
22 that people could really use and say, "There's

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1 my goal." Because I think we really have some
2 communication issues here, and we clearly
3 haven't been delivering the goods in the past.

4 MEMBER APPEL: Two points. One, I
5 think this is a huge issue, and it doesn't
6 really get adequately addressed probably in
7 the supported Institute of Medicine groups
8 that decide on these recommendations, and I
9 think if there were a panel on this, I think
10 it would be really important to try and get
11 some unifying approach where possible because
12 I think there is also biology that helps drive
13 it or not.

14 The second point is what do we do
15 now, you know, and I personally don't think we
16 should tinker with the recommendations. That
17 was actually the recommendation of the expert
18 group that met with us, but we can do things
19 to make it a bit more practical, which would
20 be as we develop the menus based on calorie
21 level to actually use adjusted values so that
22 you can put this as a footnote, and it just

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1 acknowledges the practical reality.

2 I'm sure there are going to be
3 several methodological issues into the
4 adjustment, but you might sort of reference
5 the 2000 as meeting your goals and then do
6 some adjustments as you go down and go up,
7 just as a practical issue because otherwise
8 you'll never be able to reach a sodium
9 guideline if you're in the mid-3,500, and if
10 you're an older age woman, you'll never be
11 able to meet the potassium guidelines at an
12 intake of 1,400 calories.

13 I mean, we're just setting
14 ourselves up for what I think is apparent
15 failure at both ends. I think Trish and
16 others have to really sort of think through
17 this and maybe come back to the table with an
18 approach to this issue.

19 MEMBER SLAVIN: I want to talk a
20 little bit about the fiber because it's in the
21 same category, that it really does go with
22 calorie intake, but it kind of goes the

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1 opposite way. Like for sodium, if people eat
2 less, sodium goes down, which is a positive,
3 but for fiber when people eat less, fiber goes
4 down. So it's very much linked to calorie
5 intake. So as we tell people to eat less, you
6 know, it's another example of it being linked
7 to calorie intake.

8 MEMBER NELSON: This is Mim
9 Nelson.

10 I'm wondering, Larry and
11 Christine, also more just a nod to physical
12 activity. I know that we have that. We're
13 going to be talking about that in a moment,
14 and we did that. You know, we've done it with
15 the physical activity guidelines, but I think
16 that I know you're talking about dietary, you
17 know, concerns here, but there may be a place
18 to dot in, you know, if you couple it with
19 physical activity. It's going to be nothing
20 major. It's just sort of a nod to physical
21 activity. A little bit, I think, would be
22 helpful because it's also around energy

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1 balance and the independent effects on blood
2 pressure.

3 MEMBER APPEL: Yes. You know, we
4 do take a very holistic approach to blood
5 pressure. You know, sodium is important, but
6 beyond that, you know, other aspects of diet.
7 Physical activity is clearly, you know,
8 important, but actually the data on that --
9 and I know that's not the committee's
10 responsibility -- some people have questioned,
11 you know, the physical activity data.

12 I personally am a little bit
13 agnostic. I don't know the data as well, but
14 we can -- part of the problem though, let me
15 just say, I think a lot of our recommendations
16 are driven by blood pressure. You know, it's
17 a very important biological variable, and
18 drives a lot, but in the report it's sort of
19 funny because it's very nutrient based, and
20 almost -- I'm not quite sure -- maybe at the
21 front end when we deal with sort of like our
22 conditions, you know, osteoporosis, cancer,

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1 cardiovascular disease, elevated blood
2 pressure, we present, you know, that's the way
3 we might cover it.

4 CHAIRPERSON VAN HORN: I think
5 we'd like to hear from the slug. Here's your
6 chance.

7 (Laughter.)

8 MEMBER RIMM: I hate to say this
9 is Eric Rimm.

10 Despite the nasty comment that
11 Larry made about me, I wanted to start off by
12 first congratulating USDA and HHS for picking
13 like three of the world's experts in this area
14 because I think you really have done an
15 awesome job in covering this field, and I
16 think we should be screaming this from the
17 rooftops. I think what Christine has shown us
18 is Grade 1 evidence and not Grade 2 evidence,
19 and if it really does change millimeters of
20 mercury in children that translate into
21 millimeters of mercury in adults, which
22 translates to threefold higher risk of stroke,

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1 we actually have a lot to say here.

2 And I think that sort of giving an
3 out to industry saying we know how hard it is
4 to get average intakes from 2,300 down to
5 1,500 is also giving an out because I think it
6 can be done. I mean, for ten years we've said
7 we couldn't take *trans* out of the food supply,
8 and as soon as they put *trans* on the food
9 label, two years later 50 percent of the *trans*
10 was gone.

11 So I think it can be done, and I
12 think targeting children where they haven't
13 already developed the taste for sodium is
14 probably the best place to start. I mean, I
15 don't know how much you can cover that
16 evidence, but that is sort of some of the few
17 papers that I have read that, you know, kids
18 don't have a taste for sodium until it's
19 introduced to them continually that they
20 develop the taste for sodium over time.

21 So you know, I was very impressed
22 with the presentation that you both made. You

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1 know, this is an opportunity for us to stand
2 up with the dietary guidelines saying this is
3 one of our points. It may not be related to
4 obesity, but it really is driving blood
5 pressure and stroke risk from the slug.

6 CHAIRPERSON VAN HORN: Well put.
7 And I just have to pile on that one because
8 I'm intimately familiar with the data related
9 not only to little children but even high
10 school children in as little as three weeks,
11 three weeks can adjust their taste preference
12 down to a lower level, to the point where the
13 food they were eating prior they can no longer
14 tolerate because they've adjusted already in
15 that short amount of time. So there is
16 definitely a learning.

17 MEMBER RIMM: Yes. I don't think
18 we need salt as much anymore for preservation
19 of food. I mean, clearly there was historical
20 reason to add salt, but we have now developed
21 refrigeration. So it's not as much of an
22 issue for a lot of foods. I don't know

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1 necessarily why this salt is injected into the
2 pork or into the chicken. Some of it may be
3 for processing purposes, and some of it just
4 because we have developed taste. Yeah,
5 hydration, right.

6 So there's lots of reasons why it
7 may need to be there, but obviously not all
8 chicken and all pork is injected with that
9 much sodium. So I'm not an expert in this
10 issue. Raj may know a lot more about it, but
11 it seems to me this is an opportunity to push
12 industry to say we should make a difference
13 now because, you know, if our guidelines
14 impact food nutrition programs in school lunch
15 programs, this could be a great time where we
16 start changing what is given to children in
17 the food supply.

18 MEMBER APPEL: I think that you
19 covered a lot of issues there, and some of
20 them are actually going to be covered by the
21 Institute of Medicine committee on strategies
22 to reduce sodium, and they're going to deal

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1 with, you know, some of like the sodium or the
2 taste issues and other things.

3 I was just losing my train of
4 thought. There was one point. I do think
5 though that --

6 PARTICIPANT: To just say, Larry,
7 just because the IOM is doing it why can't we
8 do it.

9 MEMBER APPEL: IOM in terms of --
10 and we can. I mean, one of the things that's
11 hard about this, and it's not hard. I mean,
12 we don't have that many questions, but what
13 we're doing is we're going beyond the
14 questions to deal with what I consider a lot
15 of the contextual important issues related to
16 accomplishing it. So that's why we, you know,
17 covered all of these issues like adjustment
18 and that sort of thing.

19 So we're going to probably have to
20 cover, you know -- we will cover taste as a
21 topic even though it probably won't be done
22 like an NEL.

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1 I do think though that we have --
2 and I don't know what the process would be,
3 you know. One of the implications is a
4 graduated reduction in salts or sodium. The
5 process is not clear for me. I presume that
6 that's not our charge. That's the charge of
7 other groups to develop that gradual approach.

8 CHAIRPERSON VAN HORN: Well, what
9 I would say -- this is Linda Van Horn -- the
10 fact of the matter is I think everything that
11 we raise as a concern will be identified as
12 something that other groups will take forward,
13 but I definitely think as you were pointing
14 out earlier, one of the issues clearly is
15 labeling of these products.

16 I mean, as we've just said, one of
17 the things that's a problem is we don't really
18 even know how much sodium is injected into
19 some of these products because of the
20 processing that occurs after the fact. We
21 were hearing yesterday about fish, for
22 example, that's getting sprayed with some sort

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1 of sodium content, brine of some kind on the
2 boat before it actually gets even processed
3 locally.

4 So, you know, these kinds of
5 behaviors and approaches need to be estimated
6 and documented and recognized so that at least
7 we have some ability to monitor and address,
8 you know, where we can begin to look for ways
9 to reduce that much sodium.

10 Roger.

11 MEMBER CLEMENS: This is Rog,
12 sitting next to the slug.

13 (Laughter.)

14 MEMBER CLEMENS: Too much salt
15 over there.

16 I appreciate your remark on the
17 pork and the poultry. Actually if you look at
18 the USDA regulations, they are now permitted
19 and actually required to inject various sodium
20 compounds to preserve, your point, Eric, one,
21 to prevent CBOT development and, two, to
22 reduce the likelihood of dehydration through

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1 the food chain process.

2 And to your other comment as well,
3 if you look at something that's fresh with
4 minimal chain distribution, you're not
5 required; you're actually prohibited from
6 injecting.

7 So if we look at the food chain to
8 your comment about big box stores, so if you
9 have something in the distribution for more
10 than two weeks, you have to do something for
11 food safety purposes, and sodium chloride
12 works better than anything else.

13 So you look at cheese, you look at
14 poultry, you look at pork. It's required by
15 law to use brine. So maybe one of the
16 challenges, do we have a substitute to brine?

17 MEMBER FUKAGAWA: This is Naomi
18 Fukagawa.

19 Along the lines of what Linda was
20 saying, I do think the other part of it, the
21 other arm is obviously educating the public
22 because I think if they know how to read the

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1 labels and potentially there are ways to
2 prepare foods that allow you to remove some of
3 the brine.

4 I mean, many years ago you salted
5 foods, but you also removed the sodium prior
6 to cooking, and so you know, hand in hand
7 would be that education.

8 MEMBER PEREZ-ESCAMILLA: This is
9 Rafael.

10 And I would say that the labeling
11 issue should be extended to restaurant menus
12 as well with the amount of eating out that we
13 do. It's very difficult to keep track of our
14 sodium if we don't have that information in
15 the restaurants as well.

16 CHAIRPERSON VAN HORN: You know, I
17 really believe in American ingenuity, and I
18 think that there's an awful lot that can be
19 done in this country. We've seen so many
20 innovations that have gone on. This challenge
21 has been put out there for the last 20 years.
22 I think it's really time, you know, to step up

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1 to this goal and really partner with industry,
2 the food industry in particular, and look for
3 ways that this can be addressed gradually over
4 time so that we can finally reduce this
5 exceedingly high level of sodium.

6 The one thing that hasn't been
7 mentioned yet that we discussed yesterday in
8 this subcommittee is the fact that many of our
9 dietary recommendations are actually made as a
10 consequence of our high sodium intake.

11 For example, the higher potassium
12 needs are likely because we have such a high
13 sodium need. This may be true of the higher
14 calcium and potassium and other
15 recommendations that we're making only to
16 compensate for our very high sodium intake.

17 So I think as we discuss the
18 recommendations overall, the lower sodium
19 intake coupled with more fruits and vegetables
20 and the good products that provide the
21 potassium and fiber and other issues that are
22 under or nutrients that are under consumed,

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1 you know, begins to build the picture as far
2 as what the food choices should be.

3 And, again, beginning as early as
4 childhood seems like it has to really be
5 emphasized in order to be effective.

6 Other comments? Roger.

7 MEMBER CLEMENS: I have a
8 question. This is Rog. Do you have any data
9 on chloride intake? Did you address that
10 particular issue?

11 The reason I bring it up, Larry,
12 is that in the '70s, you may recall there was
13 a movement to reduce sodium because of a
14 hypertension story. You probably remember
15 that, too, as well, Linda, and what happened
16 there is some members of industry pushed down
17 the sodium and pushed down the chloride, and
18 then we had some issues on the pediatric
19 population. You may recall that, Chris.

20 So do we see that as a potential
21 risk or do we have some way to morph with
22 people so we can maintain an adequate chloride

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1 issue or do you see that's not an issue right
2 now as you look at the data?

3 MEMBER APPEL: Yeah, I think we
4 should investigate it. I mean, that was a
5 pathological approach, you know, just total
6 removal of chloride from I think it was infant
7 formula.

8 MEMBER CLEMENS: It was an infant
9 formula where the regulations were permitted.

10 MEMBER APPEL: So that was an
11 experiment. That's like removing --

12 MEMBER CLEMENS: And now there are
13 regulations for minimum chloride and a minimum
14 amount of sodium

15 MEMBER APPEL: I think, you know,
16 this might be one where you just sort of rely
17 on ecologic data, you know. You have these,
18 you know, tribes in South America, the
19 Yanomami Indians, you know. There's no
20 problem with infants having hypochloric or
21 problems related to inadequate chloride
22 intake.

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1 But you know, we'll take a look at
2 it.

3 MEMBER RIMM: This is Eric Rimm
4 again.

5 I mean, I just wanted to reiterate
6 the strength of the data. I think the reason
7 I started out with my comments is because I
8 was insanely jealous that you had so many
9 clinical trials where they had looked at
10 something. I mean, going back and looking at
11 the published paper from 2006 or to look at
12 the impact of sodium and blood pressure in
13 kids, you know, there's one or two which look
14 like poor quality studies because the
15 confidence intervals are very large, and the
16 rest of them it's incredibly consistent.

17 So I agree with Xav that taking
18 the "may" out of it is clear, and also that,
19 you know, this is as strong of evidence as
20 we've seen around the table for anything we've
21 looked at.

22 MEMBER CLEMENS: Part of the

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1 problem, you know, with all of this is sort of
2 you just line things up and you count how many
3 are on the line, but there's one study that is
4 actually really interesting. It's the exit or
5 end of her study where it was a silent shift,
6 you know. A school was assigned to low
7 sodium, another one to high sodium. No
8 problem with palatability, acceptability, and
9 the intervention was over months, you know. So
10 it wasn't just a one week or one month
11 intervention, and blood pressure levels were
12 lower at the end of the day, and it was a
13 crossover design as well on the periods in
14 which they were low sodium

15 So it's a real life type of study,
16 but it gets buried, you know, in the forest
17 leaf diagram.

18 CHAIRPERSON VAN HORN: Rob.

19 DR. POST: Yeah, hi. This is Rob
20 Post.

21 I wanted to just mention, since
22 you've talked about a gradual reduction, to

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1 acknowledge that there is an IOM report that
2 was released in October, October 20th or so,
3 that does, in fact, talk to school meals or
4 reflect on Building Blocks for Healthy
5 Children in the school meals program, and
6 there is a gradual reduction that is suggested
7 for sodium looking at two-year increments and,
8 of course, eventually getting to a reduction
9 wholly by 2020.

10 MEMBER NELSON: Just quick
11 comment. I really also think we should be
12 screaming this because it's so important, but
13 also I know I've sort of brought this up
14 before, but again, this sort of strengthens
15 the issue of the shorter the supply chain also
16 probably the lower the sodium as well as other
17 issues, and I think that, you know, thinking
18 about agricultural policies and production
19 really probably could really matter here, more
20 whole foods, less processed, shorter supply
21 chain, everything else. It all helps to
22 improve the diet.

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1 CHAIRPERSON VAN HORN: The other
2 thing that I think, you know, just needs to be
3 noted is, you know, Eric was mentioning the
4 quality of the data which are impressive, but
5 we're also fortunate as a committee that we
6 have Larry Appel who has lived through all of
7 the three DASH feeding trials, which, of
8 course, established the efficacy of blood
9 pressure lowering with lower sodium, but then
10 also the free living trial, the premiere
11 study, where it was clear that people even
12 left to their own with proper education and
13 counseling and intervention were able to make
14 those adjustments and achieve the same kinds
15 of results or certainly beneficial results,
16 even those who were normotensive.

17 So there's benefit across the
18 population here that is not only efficacious,
19 but also achievable. So I think anything we
20 can do as a country to support that movement
21 really needs to be embraced.

22 Christine.

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1 MEMBER WILLIAMS: I want to
2 mention one thing, is that -- Christine
3 Williams -- that one of the advantages of
4 doing the pediatric review was going back to
5 the 1970s because a lot of the strong studies
6 were done in the '80s and '90s, and being able
7 to put that all together was quite an
8 advantage.

9 CHAIRPERSON VAN HORN: Absolutely.
10 All right. Well, that was an
11 incredibly meaty -- I guess I shouldn't say
12 that word. We talked about that yesterday --
13 rich discussion, yes, salty discussion.

14 (Laughter.)

15 CHAIRPERSON VAN HORN: Oh, all
16 right. Well, now it's time to change gears,
17 and we'll hear from Dr. Pi-Sunyer and his
18 group on energy balance and weight management,
19 which we'll also have lots to discuss, I'm
20 sure.

21 MEMBER PI-SUNYER: Thank you,
22 Linda.

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1 So this is the membership of our
2 subcommittee: myself, Rafael Perez-Escamilla,
3 Miriam Nelson, Joanne Slavin, Christine
4 Williams, and Linda Van Horn.

5 And I'd also like to thank the
6 staff for helping us so much in every way to
7 be successful in doing these reviews.

8 The topics that we're going to
9 address today are four. Rafael will start
10 with talking about energy density, and then
11 Christine will move to childhood overweight.
12 Rafael will come back and do gestational
13 weight gain, and then finally Mim will do
14 physical activity.

15 So we'll begin with Rafael and
16 energy density.

17 MEMBER PEREZ-ESCAMILLA: Thank
18 you, Xavier.

19 The questions that I'm going to be
20 addressing are to what extent is dietary
21 energy density associated with body weight,
22 and to what extent is dietary energy density

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1 associated with highly prevalent chronic
2 diseases, including Type 2 diabetes,
3 cardiovascular disease, and cancer.

4 Food energy density is defined as
5 the amount of energy in a particular weight of
6 food and is usually expressed as kilocalories
7 per gram. Dietary energy density is estimated
8 by dividing the total amount of food
9 consumption by the corresponding amount of
10 calories.

11 Our search strategy included peer
12 reviewed research articles published between
13 June 2004 and the present, and we concentrated
14 on adults, and we looked at body weight and
15 BMI as well as a number of chronic disease
16 outcomes or the risk factors associated with
17 these chronic diseases.

18 With regards to the first
19 question, to what extent is dietary energy
20 density associated with body weight, our
21 conclusion, preliminary conclusion, is that
22 low energy density diets improve body weight

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1 outcomes among male and female adults, and it
2 is important to clarify that this is based on
3 studies that have estimated energy density
4 based only on foods, that is, excluding
5 caloric and non-caloric beverages.

6 And the strength of the evidence
7 for this conclusion, we consider it to be
8 Grade I.

9 Through our review, we identified
10 17 studies four randomized controlled trials,
11 five prospective cohort studies, five cross-
12 sectional studies, and three literature
13 reviews. We found a consistent positive
14 relationship in cross-sectional and
15 prospective studies, and the randomized
16 controlled trials with free living adults
17 indicated that relationship is likely to be
18 causal.

19 And these are the randomized
20 controlled trials that we identified, and the
21 first point that I want to make is that they
22 do cover a range of body mass indices, and

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1 that in all four trials the weight loss during
2 the first year of exposure to the low energy
3 density intervention was associated or was
4 linked with improved weight loss.

5 The researchers used different
6 strategies to lower the energy density in
7 these experimental studies, and because
8 dietary energy density is largely driven by
9 the water and fat content of the diet, the
10 very common approach that is used is to
11 increase fruits and vegetables and to lower
12 fat intake.

13 In two of the studies, in the
14 Brazilian study, for example, the participants
15 were asked to consume three apples per day or
16 three pears per day or were randomly assigned
17 to consume oatmeal cookies. All the products
18 were delivered to them, and the products were
19 isocaloric, and they also had similar fiber
20 content.

21 In the study by Rolls and co-
22 workers, the 2005 one, they decreased energy

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1 density by providing participants with low
2 energy density soups, and they were randomly
3 assigned to one or two servings of soup per
4 day or to an isocaloric high energy density
5 snack, which was also provided to them. They
6 were mostly pretzels or different types of
7 chips.

8 And as I mentioned during the
9 first year, all four trials found the
10 relationship or a causal relationship between
11 lowering energy density and improved weight
12 loss outcomes, and all the trials concentrated
13 on obese and overweight adults.

14 The study by Saquib and co-
15 workers, however, found at four years of
16 follow-up these differences were no longer
17 statistically significant.

18 So to summarize the randomized
19 controlled trials, all of them found an impact
20 of low energy density on weight loss within
21 the first year, but one randomized controlled
22 trial did not find significant differences at

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1 four years of follow-up.

2 With regards to the prospective
3 cohort studies, we can see that some of them
4 included up to six, eight years of follow-up.
5 They used different dietary intake assessment
6 methods ranging from 24-hour recalls, food
7 frequency questionnaires, and food records.
8 These are the studies that did cover quite a
9 range of BMIs among participants.

10 The first four studies listed in
11 the slide were conducted in the U.S., and all
12 of them estimated energy density based on
13 foods only, that is, excluding caloric and
14 non-caloric beverages. And all four of them
15 found the association between low energy
16 density diets and better weight maintenance.

17 The only study that did not find
18 this relationship was that by Iqbal, was based
19 on two adult Danish cohorts. However, it is
20 impossible to compare the results from this
21 study with the other four because in this
22 study they estimated a dietary energy density

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1 including beverages, and that included the
2 caloric beverages as well as water.

3 So in summary, four out of the
4 five cohort studies found an association
5 between low energy density and weight
6 maintenance. The only cohort study that did
7 not find this association used a different
8 approach to estimate energy density, and it is
9 also very important to mention that these
10 studies consistently reported that low energy
11 density diets were associated with higher
12 fruit, vegetable and fiber consumption, and
13 they were lower in animal protein and total
14 and saturated fats, and this is totally
15 expected as water and fat, again, are the main
16 drivers of dietary energy density.

17 And the studies consistently
18 report that low energy density was associated
19 with higher food intake, but lower energy
20 intake.

21 With regards to cross-sectional
22 studies, all five cross-sectional studies

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1 identified since 2004, they found a positive
2 association between food based energy density
3 and weight or related indicators. And the
4 studies consistently reported, again, that
5 lower energy density was associated with a
6 dietary intake pattern characterized by a
7 higher consumption of fruits, vegetables and
8 fiber, and lower in total and saturated fat.

9 So the implications of our
10 conclusion is that, you know, the evidence, I
11 think, clearly indicates that a low energy
12 density dietary pattern that is associated
13 with beneficial body weight outcomes is
14 characterized and needs improvement in fruit,
15 vegetable, whole grain and fiber consumption,
16 and a decrease in total and saturated fat
17 consumption.

18 The research supports
19 concentrating on dietary intake patterns that
20 are low in energy density, but the evidence
21 can not necessarily be extrapolated to
22 individual selection of foods based on their

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1 energy density. Oftentimes that is the case
2 that we are the ones to select also foods that
3 are low in energy. There are dietary intake
4 patterns that are low in energy density, but
5 that includes foods relatively high in energy
6 density, such as olive oil and nuts, or even
7 foods that are relatively low in energy
8 density, less of those, such as sodas and
9 other caloric beverages.

10 In terms of the future, I think
11 there are two very key questions that we need
12 or that someone needs to address to make
13 further progress in this area, and the first
14 one, the studies, again, strongly suggest that
15 low energy density diets perhaps are having an
16 influence on caloric intake through society
17 regulation mechanism. So it begs for
18 answering the question on if the society
19 regulation is different for solids and for
20 fluids that have the same caloric content, and
21 I believe one of our subcommittees is going to
22 be looking at that.

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1 And a second question that I think
2 is very important, especially if we are going
3 to estimate energy density based on foods only
4 excluding beverages is to find out if low
5 energy density diets are associated with
6 healthier beverage intake patterns. It sounds
7 like a simple question, but it's not because I
8 can imagine the amount of debate that will
9 occur in terms of defining what is a healthier
10 beverage intake pattern.

11 So should I take questions now
12 about this or should I move on?

13 MEMBER PI-SUNYER: Yes, Linda, I
14 think we should take questions because they're
15 all very different, the different
16 presentations.

17 I just might start by saying that
18 Joanne and her committee is going to deal with
19 at least looking at the data we have so far
20 with the difference between solid and liquid.
21 So that will be the carbohydrate-protein
22 subcommittee that will be doing that.

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1 I guess we're open for questions
2 or comments..

3 MEMBER RIMM: This is Eric Rimm.

4 I had just two questions. In the
5 randomized controlled trials that were weight
6 loss trials, you said they were isocaloric. So
7 people actually were given low energy dense
8 diets and high energy dense diets, but they
9 were isocaloric?

10 MEMBER PEREZ-ESCAMILLA: No, the
11 fruits, vegetables and oatmeal cookies, the
12 equivalent that they provided in terms of
13 calories that three pears or three apples or
14 cookies was the same.

15 MEMBER RIMM: That was isocaloric.

16 MEMBER PEREZ-ESCAMILLA: That was
17 isocaloric.

18 MEMBER RIMM: The rest of the diet
19 after that obviously --

20 MEMBER PEREZ-ESCAMILLA:
21 Absolutely.

22 MEMBER RIMM: I thought you were

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1 defying laws of energy.

2 MEMBER PEREZ-ESCAMILLA: No, no,
3 no.

4 MEMBER RIMM: So, I mean, what do
5 you think based on all of this literature;
6 what would be the best proposed mechanism that
7 explains this? Clearly something about this
8 is working if you get rid of peanuts and you
9 get rid of beverages. What is driving this do
10 you think?

11 MEMBER PEREZ-ESCAMILLA: Well, it
12 seems that society, the work from Barbara
13 Rolls' group in particular, you know, strongly
14 supports the view that low energy density
15 diets lead to higher total food consumption or
16 lower energy intake. So the volume, the
17 amount of food that is consumed --

18 MEMBER RIMM: Just the physical
19 volume of it, okay.

20 MEMBER PEREZ-ESCAMILLA: -- that
21 would be Barbara Rolls' hypothesis.

22 MEMBER RIMM: So the one place

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1 where I think there is slight disagreement
2 with the fat committee is their statement that
3 the diets are driven by low saturated fat, low
4 total fat because most of the trial data on
5 total fat that we didn't summarize this year,
6 that has been summarized many times in the
7 past and by the IOM committee suggests that
8 overall low fat diet does not lead to weight
9 loss.

10 And clearly there are ways to go
11 about a low fat diet that lead to weight loss,
12 but in this country low fat diets have not led
13 to weight loss, and most of the trials don't
14 support that.

15 So I would be a little concerned
16 about having this in disagreement with the fat
17 subcommittee.

18 MEMBER PEREZ-ESCAMILLA: Okay. The
19 fact, Eric, is that the energy density of the
20 diet is largely created by the water content
21 and the fat content. There is no, I think,
22 argument in terms of that. The data is very,

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1 very clear.

2 MEMBER RIMM: You're just
3 describing what the diet is.

4 MEMBER PEREZ-ESCAMILLA: I think
5 the issue is that if it's less fat, but
6 increased fruit and vegetables, it's not just
7 less fat, but you know, it's the whole dietary
8 pattern again that has to be taken into
9 account.

10 So low energy density doesn't mean
11 anything. The meaning is what is the dietary
12 pattern that is linked with them, and are
13 those dietary intake patterns beneficial or
14 not.

15 And study after study is showing
16 that the dietary intake pattern associated
17 with low energy dense diets that is beneficial
18 is carrying fruits and vegetables and lower in
19 fat.

20 MEMBER RIMM: Okay. Well, that's
21 good, and I think it's a good description of a
22 dietary pattern.

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1 MEMBER PEREZ-ESCAMILLA: Yeah,
2 yeah.

3 MEMBER APPEL: Larry Appel.

4 That was really interesting. I
5 have a question, and it's trying to integrate
6 yesterday's presentations with this. So we
7 didn't see much relationship with, you know,
8 fruit and vegetable with weight, you know, and
9 is that because that was just too narrow, you
10 know, and it's only dealing with sort of, you
11 know, one piece, whereas sort of this energy
12 density, you know, seems to cover the whole
13 diet?

14 Because I think you're left with
15 yesterday being, well, fruit and vegetables
16 don't really matter, but then I listen to you
17 and fruit and vegetables matter a lot, you
18 know.

19 And so it seems like -- I mean, is
20 it just that their piece was only too focused,
21 too narrow?

22 MEMBER PEREZ-ESCAMILLA: I think

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1 it goes back to Mim's point from yesterday
2 that we really have to be careful with food
3 group approach. It's really, really difficult
4 to get, I think, relevant conclusions for
5 advising the public because everything has to
6 be placed in the context of the dietary
7 pattern.

8 MEMBER APPEL: The second thing,
9 how are you -- I mean, you know, I think this
10 is actually an advance in the evidence since
11 2005 -- how are you thinking of the
12 translation piece because we've had problems
13 with you're basically talking about a ratio,
14 you know, and that's not easy to translate. So
15 are you still thinking about even though we
16 can't do the evidence based on food groups to
17 still go back to food groups, or how are you
18 thinking about this or how have people done
19 this?

20 MEMBER PEREZ-ESCAMILLA: Well, as
21 far as I know energy density of diets has not
22 been specifically included in a logo or a food

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1 label symbol for people to select them based
2 on energy, energy density, and I don't think
3 that would be the right approach.

4 I think at the end of the day the
5 recommendation needs to be based on the
6 pattern, on the dietary pattern and not on the
7 energy density of individual foods.

8 CHAIRPERSON VAN HORN: I think the
9 other thing that we can intertwine into this
10 discussion is the wonderful presentation we
11 heard a couple of meetings back from Frank
12 Sacks in terms of his excellent comparison of,
13 you know, shifting the energy composition from
14 fat to, you know carbohydrate to protein, et
15 cetera, and as we all remember, you know, the
16 take home message from that was it doesn't
17 matter. Pick one, you know. It's all about
18 calories. It's about the idea that if you're
19 trying to lose weight, it's a matter of
20 recognizing that the adherence to the dietary
21 pattern that is your preference is perhaps one
22 of the better ones.

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1 I think Barbara Rolls' work sort
2 of suggests that, that if you are satisfied
3 with a diet that is high in volume, then, you
4 know, there's no question that a low energy
5 dense diet is going to include more fruits,
6 vegetables and lower calorie foods in order to
7 give you the satiety that a high fiber, you
8 know, type of diet would give you, as opposed
9 to some who might prefer the concentrated
10 sources of fat, but also controlling the total
11 number of calories.

12 So I think that where we're going
13 in terms of the research based on Frank's
14 study, which was, I think, in many people's
15 estimation a fairly conclusive documentation
16 of that very principle, and I would point out
17 that he also showed us two-year follow-up data
18 if you recall with minimal ongoing
19 intervention and yet continued adherence to
20 these dietary patterns.

21 So I think that the whole issue
22 that we need to address here is both the

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1 message up front, the adherence established,
2 and then the ongoing reinforcement of that
3 message to sustain and maintain that type of
4 dietary intake.

5 MEMBER PEREZ-ESCAMILLA: I totally
6 agree, and I think the words "sustain" and
7 "maintain" is very key because I think in
8 terms of where the research needs to go is
9 also in the type of dietary patterns that
10 people can really maintain for the long term
11 because that's another key question.

12 MEMBER PI-SUNYER: Okay. I think
13 we need to go on because we've got three more
14 to do. Our next topic is childhood
15 overweight, and Dr. Christine Williams will
16 present that.

17 MEMBER WILLIAMS: Thank you, Xav.

18 I'll be presenting several
19 questions related to childhood overweight and
20 obesity this morning.

21 MEMBER PEREZ-ESCAMILLA: I'm
22 sorry. I thought I got off. Okay. Thank

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1 you.

2 Very good. So now I'm going to
3 talk about -- here we go. So now the question
4 is to what extent is dietary energy density
5 associated with Type 2 diabetes, and in this
6 instance the evidence is just starting to
7 emerge. We were only able to identify three
8 studies. So that's why it's Grade III at this
9 point.

10 However, in agreement with the
11 association between energy density and body
12 weight, the few available studies find the
13 consistent association between energy density
14 and risk for Type 2 diabetes or its risk
15 factors. The implication is that promoting
16 lower energy density dietary intakes may be
17 associated with lower risk of Type 2 diabetes,
18 although the results obviously need further
19 confirmation.

20 And the studies that we identified
21 were two European cohort studies. The one
22 conducted in the U.K. included a ten-year

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1 follow-up, the one in Finland a three-year
2 follow-up, and the one from Finland is derived
3 from a randomized diabetes prevention trial,
4 but they pooled the groups for this analysis.

5 And in both studies they
6 ascertained a Type 2 diabetes either through
7 biochemical blood measures or through clinical
8 files, and the findings from the cohort
9 studies were confirmed in the U.S. by Jason
10 Mendoza and colleagues who analyzed NHANES
11 data and found the relationship between higher
12 energy density diets and higher fasting
13 insulin levels.

14 All three studies adjusted for
15 caloric intake, suggesting that there may be
16 something about dietary composition that goes
17 well beyond calories in terms of perhaps
18 explaining these relationships.

19 The two European studies included
20 caloric level addressed in the energy density
21 estimation. The NHANES study did not. It
22 excluded all beverages as most of the studies

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1 in the U.S. do.

2 With regards to cancer, to what
3 extent the dietary energy density associated
4 with cancer, the conclusion is that evidence
5 for energy density and cancer is indirect and
6 extrapolated from energy density and body
7 weight studies, and our main source of
8 evidence for this conclusion is the World
9 Cancer Research Fund report, and that's why we
10 didn't grade it, but we did not -- we were
11 unable to identify studies examining directly
12 the relationship between energy density and
13 cancer.

14 MEMBER WILLIAMS: Thank you.

15 Christine Williams.

16 I'll be addressing several
17 questions related to childhood overweight and
18 obesity, and of course, these questions are
19 fueled by the increase in childhood obesity in
20 the U.S. over the past several decades. For
21 children between the ages of two and 19,
22 almost one-third are currently obese.

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1 The first question is the
2 pediatric side of the energy density question.
3 To what extent is dietary energy density
4 associated with childhood overweight and
5 obesity?

6 And then I'll move on and discuss
7 is intake of fruit and vegetables, not
8 including juice, related to adiposity in
9 children, and second is intake of 100 percent
10 fruit juice related to adiposity in children?

11 The definitions that we'll use for
12 childhood overweight and obesity, for obesity
13 BMI equal or above the age and gender specific
14 95th percentile on the 2000 CDC growth charts,
15 and overweight being between the 85th and 94th
16 percentile.

17 For energy density, since this was
18 a new question we took the search back to
19 January of 1980. We looked at studies related
20 to children between the age of birth and 18
21 years of age. We included only studies that
22 actually calculated energy density and used

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1 the objective measure of adiposity.

2 For the question to what extent is
3 dietary energy density associated with
4 childhood overweight and obesity, proposed
5 conclusion is that energy dense diets increase
6 adiposity and the risk of overweight and
7 obesity in children with a Grade III limited
8 evidence.

9 In this review we found seven
10 studies. Five articles recorded findings from
11 three different longitudinal cohorts and two
12 cross-sectional studies. All of the studies
13 were conducted outside of the U.S., published
14 between 2004 and 2009. Five studies found a
15 positive association between dietary energy
16 density and adiposity.

17 The majority of studies that
18 reported a positive association were
19 methodologically strong and calculated dietary
20 energy density by methods that excluded all or
21 most beverages. They were also primarily
22 longitudinal cohort studies and used objective

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1 measures measuring adiposity, including DEXA
2 or doubly labeled water.

3 The next question is with fruits
4 and vegetables. Is intake of fruits and
5 vegetables, not including juice, associated
6 with adiposity in children? Our proposed
7 conclusion, intake of fruits and vegetables,
8 especially fruit, is inversely associated with
9 adiposity in children with a Grade II moderate
10 evidence.

11 Our approach to this review, we
12 combined the evidence from two independent
13 systematic literature reviews. The American
14 Dietetic Association's evidence analysis
15 library review covered the dates between
16 January 1982 and September of 2004, and then
17 our NEL review covered this covering, with a
18 little overlap, January 2003 through July 2009

19 We found a combined review of --
20 in combination we reviewed 24 articles.
21 Eighteen were from the earlier ADA and longer
22 ADA review, and six from the current NEL

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1 review.

2 There was one trial, six
3 longitudinal studies of five cohorts and 17
4 cross-sectional studies, two of them involving
5 nationally representative samples of children.

6 In summary, ten of the studies
7 found an inverse protective association
8 between fruit and vegetable intake and
9 adiposity. Twelve found no association
10 between fruit and vegetable intake and
11 adiposity. One found no association between
12 usual intake, but a positive association for
13 children with increased recent intake, and one
14 found no association between consumption of a
15 vegetarian diet and adiposity.

16 On average, U.S. children do not
17 consume fruit and vegetables in the amounts or
18 variety that are recommended. The mean intake
19 of fruits for children is only about one
20 serving a day for four to 18 year olds and one
21 and a half servings for one to three year
22 olds.

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1 Mean intake of vegetables, only
2 about one serving a day for one to eight year
3 old children and one and a half to 1.5
4 servings a day for older children, and for
5 older children white potatoes often served as
6 french fries or potato chips represent a
7 significant portion of total intake, and
8 intake of dark green and orange vegetables is
9 very low.

10 So for fruits and vegetables,
11 increasing consumption of fruits and
12 vegetables in childhood is an important public
13 health goal not only from the perspective of
14 increasing the intake of shortfall nutrients,
15 but also since diets high in a variety of
16 fruits and vegetable tend to be lower in
17 energy density and, therefore, likely to
18 improve energy balance and prevent obesity.

19 Moving on to 100 percent fruit
20 juice, the question is is intake of 100
21 percent fruit juice associated with adiposity
22 in children. Proposed conclusion is that for

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1 most children intake of 100 percent fruit
2 juice is not associated with increased
3 adiposity unless consumed in large quantities
4 at or above 12 ounces a day.

5 However, intake of 100 percent
6 fruit juice has been associated with increased
7 adiposity in children who are overweight or
8 obese. Thus, 100 percent fruit juice can be a
9 healthy part of a child's diet when consumed
10 in moderation as part of a nutrient rich
11 energy balanced diet.

12 The approach to this review,
13 again, was based on the combination of two
14 independent systematic literature reviews, the
15 first from the American Dietetic Association,
16 from 1982 to September of '04, and then our
17 subsequent NEL review from 2003 to 2009.

18 In combination, this resulted in
19 25 articles, 15 from the ADA review and ten
20 from our subsequent NEL review. There were 12
21 longitudinal cohort studies and 13 cross-
22 sectional studies of which four were

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1 nationally representative samples of U.S.
2 children.

3 Sixteen of them found no
4 association between fruit juice and adiposity.
5 Five found a positive association between
6 fruit juice and adiposity. Two found
7 differing results by gender, and two found no
8 association in normal weight children, but a
9 positive association for children who were at
10 risk of overweight or overweight.

11 So, in summary, 100 percent fruit
12 juice can be a healthy part of a child's diet
13 when consumed in moderation as part of a well
14 balanced diet. Consumption of whole fruits
15 rather than 100 percent juice is likely to
16 confer greater health benefits, particular
17 increasing dietary fiber and also potassium.

18 Since about one-third of U.S.
19 children are currently overweight or obese,
20 it's important though to control calorie
21 intake and choose nutrient dense foods and
22 beverages for daily consumption.

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1 I think that's it.

2 MEMBER PI-SUNYER: Thank you,
3 Christine.

4 Any comments or questions?

5 MEMBER APPEL: This is Larry
6 Appel.

7 In 2005 there was -- I guess it
8 had to do with a lot of this literature. You
9 know, you didn't have particularly cross-
10 sectional studies, but also with cohort
11 studies, great data concurrently on physical
12 activity as well as diet, and I'm just
13 wondering -- and we all know that some studies
14 have ability to stratify or adjust and do
15 other things -- is there any study in this
16 that sort of stands out as being really a well
17 done study that has, you know, the ability to
18 look at physical activity and control for it
19 and look at an independent relationship?

20 Because there is, you know, a good
21 possibility of having a null result here if
22 you don't.

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1 MEMBER WILLIAMS: I think the
2 studies from the U.K., the ALSPAC studies,
3 three of the cohort studies were from that
4 single cohort, and they were excellent
5 studies. I think they did try to control for
6 as many confounders as possible, and physical
7 activity was one of them.

8 They really stand out as I think
9 the best studies of the lot.

10 MEMBER APPEL: And what were the
11 results of those studies?

12 MEMBER WILLIAMS: They found that
13 dietary energy density was associated with
14 adiposity, but higher energy density.

15 MEMBER APPEL: I mean for --

16 MEMBER WILLIAMS: Oh, are you
17 talking about fruit juice?

18 MEMBER APPEL: Yeah.

19 MEMBER WILLIAMS: For fruit juice,
20 no, I can't say. I think of all the studies,
21 some of them, perhaps a third to a half, tried
22 to get some measure of physical activity, but

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1 usually it was very rough. I can think of
2 perhaps one that actually measured physical
3 activity by accelerometer.

4 MEMBER PEREZ-ESCAMILLA: Christine,
5 one comment that I want to make based on your
6 energy density and my energy density
7 presentation on that, as with sodium and blood
8 pressure and so on, this is another area where
9 there is a remarkable consistency in terms of
10 what we're finding with adults and with
11 children, although with children there is
12 still not enough -- I don't think there is any
13 randomized trial, but it's looking also at an
14 area where we may want to start early in life
15 dealing with that issue.

16 MEMBER RIMM: This is Eric Rimm.

17 It was a very nice presentation. I
18 think that the one part that worries me a
19 little bit, and maybe you can speak to this as
20 to the data, is it almost seems like we're
21 setting 12 ounces of fruit juice as a target,
22 and the fact that you're overweight, your 100

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1 percent fruit juice conclusions start out with
2 saying it can be a healthy part of a diet. I
3 can already see how that's being translated
4 into everybody should have 12 ounces of fruit
5 juice.

6 The important part that may be
7 missed is that one-third of the kids are
8 overweight and should probably be having a lot
9 less, and I think your second conclusion is
10 probably much more important than your first
11 conclusion, is that it probably should be
12 consumed as whole fruits rather than 100
13 percent juice because of the other benefits
14 that we're all talking about.

15 So, you know, getting back to
16 Larry's point, you know, are a few of these
17 studies stronger than others in terms of where
18 did that 12 ounces come from? Because that's
19 the part that -- I don't know how many
20 calories are in 12 ounces of fruit juice, the
21 typical fruit juice, but I can imagine --

22 MEMBER WILLIAMS: It's a big

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1 glass.

2 MEMBER RIMM: Well, it's 160. So
3 I can imagine that's ten to 15 percent of the
4 caloric intake for a child, and I hate for
5 that to become the target. Where did that 12
6 ounces come from?

7 MEMBER WILLIAMS: Well, there were
8 several studies that actually looked at the
9 amount of fruit juice, and there were at least
10 three that showed that at or above 12 ounces,
11 that's when you began to see more of that
12 positive effect.

13 MEMBER RIMM: So the issue is, I
14 guess, that some of that measurement error is
15 that you can't capture the subtleties or is it
16 something that's getting lost in physical
17 activity? Because it just seems to defy the
18 caloric --

19 MEMBER WILLIAMS: I think some of
20 the studies were better able to measure the
21 amount of juice, but if you look at the
22 recommendations in various groups, the

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1 American Academy of Pediatrics has defined the
2 amount of fruit juice that should be consumed
3 at each age, and actually the new guidelines
4 from NHLBI are even more conservative,
5 recommending smaller amounts.

6 All of the guidelines from the
7 USDA in the past have recommended whole fruits
8 rather than 100 percent juice and emphasized
9 that.

10 MEMBER RIMM: So I wonder if we
11 should try to sort of -- not necessarily
12 because we want to be in line with everybody
13 else, but sort of point to the NHLBI or to
14 others to say that, you know, that's pretty
15 strong evidence that we should be having less
16 than 12 ounces.

17 MEMBER WILLIAMS: I think
18 originally the ADA conclusion was similar to
19 ours, except they had said unless consumed in
20 very large quantities, and when we discussed
21 this earlier, we decided to put a number to
22 that, which was what was found in several of

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1 those studies that was at or more than 12
2 ounces.

3 So it's a toss-up as to how you
4 want to mention that, but it's large
5 quantities. So there's a problem usually.

6 CHAIRPERSON VAN HORN: The point
7 you're making, Eric -- this is Linda -- you
8 know, is really a very important one. I am
9 familiar with NHLBI recommendations, and they
10 actually advocate no more than four ounces of
11 100 percent fruit juice per day for children
12 because the caloric content can be anywhere
13 from 150 to 300 calories a day, which for a
14 child is just, you know, way more than should
15 be consumed in that context.

16 So I think that's a point that's
17 very well taken. What the data show from, you
18 know, studies that involved a whole bunch of
19 different diet assessment methods also, you
20 know, raised some questions about specifics
21 related to the weight issue. So I think
22 that's really important.

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1 MEMBER NICKOLS-RICHARDSON: And
2 this is Shelly.

3 I just want to also echo that
4 comment because I think the reconciliation
5 between the energy density work that excludes
6 these liquids, these beverages, that there has
7 to be some connection here. So I think that
8 the 12 ounces is probably beyond what we
9 really want to recommend in relation and in
10 light of the energy density of the diets and
11 weight relationship and the fruit and
12 vegetable consumption in relation to dietary
13 fiber.

14 MEMBER PI-SUNYER: Yes, this is
15 Xavier.

16 I think the fiber issue is
17 important and should be emphasized. So I
18 would agree with Eric in a way that maybe you
19 should reverse those and put fruits and
20 vegetables, you know, as versus juice as being
21 the first recommendation.

22 MEMBER NELSON: This is Mim.

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1 But I would reverse them, but I
2 guess I also support not having 12 ounces
3 unless there was a really good study or a
4 couple of studies that you felt really
5 strongly that 12 ounces is just fine. I think
6 a little bit like alcohol, you know, less may
7 be better. You know, if you don't drink, it's
8 probably more strong; that if you don't drink
9 juice, don't start drinking juice.

10 (Laughter.)

11 MEMBER NELSON: No binge juice
12 drinkers.

13 But I just think that less is more
14 and more whole fruit is better, sort of that
15 theme.

16 MEMBER WILLIAMS: I appreciate
17 your comment. I think that 100 percent fruit
18 juice though in moderation can still be a
19 nutritious part of a child's diet. Not all
20 juices are created equal, but there are some
21 nutrients that are significant and provide
22 benefits to children. So I would not want to

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1 recommend no juice, but I think in moderation.

2 MEMBER PI-SUNYER: Tom.

3 MR. PEARSON: Chris, just trying
4 to look back at yesterday's discussion on our
5 nutrient adequacy and the yellow, red and
6 leafy green ones, I'm just wondering about the
7 recommendation obviously as to eat a variety
8 of fruits and vegetables, but I wonder if you
9 want to be stronger than that.

10 I mean your statement is obviously
11 that real deficiencies were in those two
12 groups, and with the dominance of potato based
13 that's kind of getting away with fruits and
14 vegetables. I'm not sure you'd get as far as
15 you'd like to be unless you specifically
16 talked about the red, yellow, and leafy
17 greens.

18 MEMBER WILLIAMS: I agree, and I
19 think in the write-up of the chapter that will
20 definitely be emphasized because I think
21 second to potatoes comes tomatoes. So that
22 when we include all of those together, it will

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1 give us a better picture of the variety of
2 fruits and vegetables being consumed.

3 MEMBER ACHTERBERG: This is
4 Cheryl.

5 If I could do a quick follow-up on
6 the potato issue here, that is to come. We're
7 going to do some more food modeling and take a
8 look at how we might reposition that as a
9 possibility.

10 MEMBER SLAVIN: This is Joanne.

11 I just wanted to mention, too, for
12 Christine that her question really wasn't
13 fruits and vegetables. You know, so if you go
14 back to her question -- right, exactly, and
15 that's what was answered. So I think there's
16 other things that will come along with some of
17 the other questions that have been asked.

18 MEMBER NELSON: But she did answer
19 fruits and vegetables. Yeah, there were both.
20 There were two different questions. One was
21 just about fruits and vegetables, and one was
22 just about fruit juice.

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1 MEMBER SLAVIN: Right, but I think
2 for this last one, for the amount of fruit
3 juice when you do the evidence based review
4 and their amounts, I think people are going to
5 be looking for that.

6 So in doing that evidence based
7 review, you know, I think the 12 ounces,
8 she'll have to go back and think about how
9 that was in there, where that came from.

10 MEMBER PI-SUNYER: Rafael.

11 MEMBER PEREZ-ESCAMILLA: Christine
12 --

13 MEMBER ACHTERBERG: This is
14 Cheryl.

15 I just want to ask the committee
16 to consider behavior and family choices in
17 real life, too. When parents give their
18 children juice, are they thinking of it as a
19 serving of the fruit group or are they
20 thinking of it as a healthier beverage than
21 maybe soda?

22 So the issue I think we need to

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1 sort through here is really on the beverages
2 themselves and how many ounces of beverages
3 are we recommending, and of that what kind of
4 beverages, and then look at the foods and what
5 kinds of foods we want people to eat.

6 Because I think as nutritionists,
7 we're sort of pulling them together because we
8 know what the nutrient profiles look like, but
9 in practice people have to give thirsty
10 children something to drink, and they're
11 making a choice that is perhaps totally
12 independent of the way they're thinking of the
13 rest of the diet.

14 MEMBER WILLIAMS: This is
15 Christine again.

16 I think, well, fruit juice is
17 considered a serving of fruit, but the
18 question is to serve it in moderation, but
19 again, parents do have the perception that it
20 is a very healthy beverage, and that if some
21 is good, more may be better, and really it's
22 an educational issue to say that fruit juice

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1 is good but in certain amounts and to help
2 them understand the caloric needs of their
3 child, which often they don't, and to keep
4 them within a certain energy range.

5 MEMBER ACHTERBERG: This is Cheryl
6 again.

7 I guess what I'm trying to say is
8 we might need some kind of advice. I don't
9 know if I should call it a recommendation yet,
10 but some kind of advice on beverages, maybe
11 also potatoes, but on beverages per se and how
12 to divide those rather than -- you know, as
13 nutritionists we can slot them a fruit juice
14 as a fruit, but as people trying to follow
15 advice, I think we need more advice about
16 beverages per se.

17 And most of the studies we're
18 reviewing exclude fruit juices. So we have to
19 consider that as well.

20 MEMBER WILLIAMS: It's Christine.

21 I think that's a very good point,
22 and there has been a big shift in beverage

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1 consumption among children and adolescents
2 over the past couple of decades, and I think
3 to put more emphasis on best choices would be
4 excellent.

5 MEMBER SLAVIN: I guess I just
6 want to put in a plug for protein, too. If
7 we're limiting calories and looking at
8 choices, that a lot of times getting protein
9 into the diet, fruit juice, especially 12
10 ounces, is a lot of carbohydrate that probably
11 with calorie needs needing to go down doesn't
12 fit into a lot of diets.

13 MEMBER PEREZ-ESCAMILLA: This is
14 Rafael.

15 One issue I want to bring up to
16 recommend is I've done quite a bit of research
17 with low income Latinos, and we have collected
18 data among other things on fruit juice
19 consumption, and people report as 100 percent
20 fruit juice a lot of things that you would be
21 very surprised, and there is a big problem in
22 terms of labels and the huge signs that say

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1 100 percent Vitamin C in beverages that may
2 contain no fruit juice at all or big signs
3 that says contains fruit.

4 So I think this is an issue that
5 we have to deal in terms of labeling practices
6 because it is very misleading especially for
7 low income consumers what 100 percent fruit
8 juice is or not when they see a product.

9 MEMBER PI-SUNYER: We need to move
10 on, and our next topic, we come back to Rafael
11 and talk about weight gain, gestational weight
12 gain.

13 MEMBER PEREZ-ESCAMILLA: Thank
14 you.

15 Again, Xavier.

16 So our subcommittee is looking at
17 the question as to how does gestational weight
18 gain impact short and longer term pregnancy
19 outcomes, and the source of the evidence is
20 the IOM report, Weight Gain During Pregnancy,
21 recently released, and it is available to the
22 public free of charge.

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1 This report was called for under
2 the leadership, under the Institute of
3 Medicine that charged 14 committee members to
4 recommend revisions to the existing guidelines
5 that had previously been issued in 1990, and
6 they wanted for the committee to take into
7 account the needs of the specific populations
8 based on the pre-pregnancy BMIs as well as
9 other demographic characteristics.

10 And they wanted the committee to
11 consider a range of approaches to promote
12 appropriate weight gain during pregnancy and
13 identify gaps in knowledge for future
14 research.

15 This question is of enormous
16 importance because American women of child
17 bearing age are now more socioeconomically,
18 ethnically, racially diverse. They're having
19 more multiple, you know, twin and triplet,
20 pregnancies, and women in the U.S. are now
21 older than before at the age that they are
22 getting pregnant.

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1 Obviously, the big issue that we
2 have to deal with is that also two-thirds of
3 women of reproductive age in the U.S. are
4 either overweight or obese, and although there
5 may be some encouraging signs that the obesity
6 increase, the overweight increase is tapering
7 off, it is very discouraging to see at the
8 bottom of the slide that morbid obesity or
9 extreme obesity, women with a BMI above 40
10 kilograms per meter squared has increased
11 recently. We're now at a point where the
12 percent of women that are morbidly obese is
13 three times larger than the percent of women
14 who are underweight. So this is a group we
15 need to keep in mind.

16 The need for this work becomes
17 very obvious when you see the slide that shows
18 the distribution of gestational weight gain
19 appropriateness, as judged by the 1990 IOM
20 guidelines, and you can see that the
21 percentage of women that are meeting the
22 gestational weight gain guidelines ranges from

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1 50 percent underweight -- that do not meet the
2 guideline ranges from 50 percent among
3 underweight women to 70 percent, 73 percent
4 among overweight, obese women, and among
5 underweight women the biggest problem is not
6 gaining enough weight. Among overweight,
7 obese women the biggest problem is that they
8 are gaining excessive amounts of weight during
9 their pregnancy.

10 The guidelines that have just been
11 released, the committee used a new approach.
12 It's based on taking into account the
13 inevitable tradeoffs that occur in maternal
14 and child health outcomes as you consider
15 different gestational weight gains.

16 So it commissioned for analysis to
17 different groups, and a very inferential
18 analysis is the one that was derived from the
19 Danish cohort study, and in this case I want
20 to orient you because to this slide there is a
21 lot of data in here, and first of all I want
22 to mention that this data applies to

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1 primiparous Danish women.

2 Each quadrant represents a group
3 of women based on pre-pregnancy BMI. For each
4 graph on the X axis we have the amount of
5 gestational weight gain. So low means less
6 than ten kilograms. Very high means above 19
7 kilograms.

8 On the Y axis we have the
9 probability of an outcome occurring adjusting
10 for age, parity smoking and drinking status.
11 The outcomes plotted are small for gestational
12 age, large for gestational age, maternal
13 postpartum weight retention, and emergency C
14 section.

15 Because the outcomes that were
16 most responsive to gestational weight gains
17 were small for gestational age and maternal
18 postpartum weight retention, I want you to
19 concentrate in each quadrant for the point
20 where the two curves intersect. What you can
21 see is that as we move from the underweight to
22 the obese women, the point where the small for

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1 gestational age and the postpartum weight
2 retention curve crosses is at lower
3 gestational weight gain, meaning that as pre-
4 pregnancy BMI goes up, the amount of
5 gestational weight gain should be less.

6 In addition to these maternal-
7 child outcomes, the committee took into
8 account the risk of childhood obesity
9 associated with excessive weight gain. These
10 two pieces of evidence provided the key data
11 for the final risk analysis that helped inform
12 the new recommendations.

13 So as you can see, first of all is
14 that the new recommendations for underweight,
15 normal weight and overweight based on pre-
16 pregnancy BMI are identical to those issued in
17 1990, and however, for obese women this time
18 the committee provided a range of recommended
19 gestational weight gain.

20 What did change though in these
21 guidelines is that the classification based on
22 pre-pregnancy BMI is now being based on the

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1 World Health Organization or the NHLBI
2 criteria instead of the previous criteria used
3 in 1990 based on the Metropolitan tables, life
4 insurance tables.

5 I do want to mention that the
6 range for the obese women is mostly, if not
7 solely, based on Class 1 obese women because
8 we have not enough data for morbidly obese
9 women to come up with a more refined
10 recommendation by the level of obesity.

11 Also, the committee came for the
12 first time with recommendations for
13 gestational weight gain, and these are
14 provisional for mothers that deliver twins.
15 They are provisional because they are derived
16 from a single large study that is still
17 ongoing in different states in the U.S.

18 And what we did was to look at
19 women who delivered twins and both twins were
20 delivered at term and both weighing over 2,500
21 grams. Unfortunately there were not enough
22 women who were underweight pre-pregnancy that

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1 met this criteria. So we couldn't come up
2 with a provisional recommendation for them or
3 for the rest of categories. This is what they
4 are.

5 The committee commissioned
6 additional analysis to see if we needed to
7 make special recommendations, for example, for
8 women of short stature, teenage women,
9 different racial-ethnic groups, primiparous
10 women, and smokers, and we did not find
11 evidence to support making special
12 recommendations, although the Danish data in
13 particular does suggest that perhaps
14 primiparous women would benefit from a little
15 bit more gestational weight gain during
16 pregnancy and that perhaps they should be
17 gaining towards the upper end of the range.

18 However, these data come from
19 Denmark. They have much lower levels of
20 obesity, overweight in that country. So we
21 didn't find justification to make a special
22 recommendation, but obviously more work is

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1 needed.

2 And what this slide shows are the
3 medium gestational weight gain. What you have
4 on the light blue bars is the median and the
5 interquartile range of what women are actually
6 gaining based on their pre-pregnancy BMI in
7 the U.S., and in the dark bars what you have
8 is the recommendation, basically the range and
9 the median with any recommendations, and the
10 first issue that you can notice is that we
11 have an enormous work to do when it comes to
12 overweight and obese women because they are
13 gaining, much, much more weight than what they
14 should during gestation.

15 And even with underweight women,
16 although the medians look pretty close, still
17 25 percent of underweight women in these data
18 were gaining less than recommended and 25
19 percent were gaining more than recommended.

20 So there is work to do across the
21 board, but you can see that we have an
22 enormous amount of work to improve adherence

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1 to gestational weight gain guidelines among
2 overweight and obese women.

3 So the conclusions from the
4 Institute of Medicine, and I want to clarify
5 these are not from our subcommittee, but they
6 are from the Institute of Medicine report, is
7 that really the guidelines are not that
8 different. You know, 20 years have passed,
9 and things are not looking good. They are
10 looking worse, but the problem was not that
11 the guidelines were not adequate. If they had
12 been followed more, we would have had much
13 less of the problems with maternal and child
14 health than we have now.

15 And what it really takes is a
16 different way of thinking about how to improve
17 the BMI with which women arrive to pregnancy,
18 the pre-conceptual body mass index, and how
19 to promote better gestational weight gain
20 guidelines during pregnancy and obviously
21 issues related to post conceptual and
22 postpartum weight retention.

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1 And very quickly, what I want to
2 mention about pre-pregnancy BMI, you know,
3 this committee was charged with looking at
4 gestational weight gain controlling for pre-
5 pregnancy BMI, but when you look at the
6 evidence, pre-pregnancy BMI is by far a more
7 powerful determinant of the same outcomes.

8 So this is another area where we
9 want to do everything we can to do primary
10 prevention, and we need to start very early on
11 in life.

12 Thank you.

13 MEMBER PI-SUNYER: Thank you,
14 Rafael.

15 I think that chart he showed of
16 the overweight and obese individuals and how
17 far away they are from the recommended is very
18 serious, and you saw his slide of showing the
19 inexorable going up of weight retention as
20 women get heavier over time. So it is a huge
21 issue here.

22 We're open for questions.

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1 MEMBER FUKAGAWA: This is Naomi.

2 I have a -- oh, sorry. Somebody
3 else?

4 Do we know the sort of major
5 factors that are influencing the excessive
6 weight gain in the overweight? Is it intake
7 or is it decreased -- well, you know what I'm
8 asking.

9 MEMBER PEREZ-ESCAMILLA: That is
10 one of the most important research
11 recommendations. There is so, so little data
12 on dietary intake patterns during pregnancy
13 and how they relate to gestational weight
14 gain, and it's data that is needed not only
15 for generally during pregnancy, but by
16 pregnancy trimester because there are lots of
17 questions also about the timing of exposure to
18 different diet compositions and so on.

19 So that's a great question. We
20 couldn't even develop a chapter on that
21 question because of the lack of data on
22 dietary intake during pregnancy and how it

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1 relates to gestational weight gain and
2 pregnancy outcome.

3 MEMBER WILLIAMS: Christine
4 Williams.

5 I think for the majority of young
6 women, the obstetrician-gynecologist is also
7 their primary care physician, and the question
8 is how much primary care in this area of
9 nutrition and weight control are they getting,
10 and I suspect it isn't enough.

11 So I think we really need to work
12 with the guidelines for how young women are
13 treated by their primary care physicians.

14 And also, I think with women when
15 they are first pregnant usually they're
16 encouraged to gain weight. Don't worry about
17 the weight gain, and then by the time that the
18 physician is concerned about the weight gain
19 the horse is already out of the barn and it's
20 excessive.

21 So there are a lot of
22 considerations there as far as meeting the

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1 guidelines.

2 MEMBER PEREZ-ESCAMILLA: Yes, and
3 you're just reminding me of one issue. The
4 worst time period to advise women to lose
5 weight is during pregnancy. So really what we
6 need to talk about is maintaining the
7 healthiest gestational weight gain.

8 The committee was very concerned,
9 for example, of even making a statement about
10 morbidly obese women perhaps not needing to
11 gain any weight. So we really are in very
12 dangerous territory when we get to weight
13 loss, which I know that's not what you meant,
14 but in terms of the health care providers and
15 how they interpret what we're saying, my group
16 has done research with low income pregnant
17 Latinas asking them about whether gestational
18 weight gain came up as a topic of discussion
19 when they saw their OB-GYNs, and for over half
20 of them it didn't, and for those that it did
21 it wasn't like setting a goal or coming up
22 with a dietary physical advice kind of

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1 counseling. There is almost zero in terms of
2 that.

3 So I thoroughly agree with you,
4 Christine, that we have to work with the
5 health care providers on the dissemination of
6 the findings from this report.

7 MEMBER APPEL: Larry Appel.

8 That was really interesting, and
9 also quite important. What I'm struggling
10 with is how it fits in the report because
11 obviously, you know, we're not obstetricians
12 here, but I think we'd feel uncomfortable --
13 perhaps many would -- about commenting on
14 that, period.

15 But how have you thought of that,
16 you know, what we're going to say and where
17 we're going to say it?

18 MEMBER PI-SUNYER: I think, you
19 know, we're dealing with different groups. We
20 are dealing with children, and we're dealing
21 with adults, and I think this is a group at
22 risk, and I don't see any problem in putting

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1 it in as a subgroup that we're concerned about
2 with regard to weight gain and eventual
3 continuing obesity over time. So I don't see
4 it as a problem.

5 MEMBER APPEL: I was thinking more
6 about recommendations. The concern is
7 obviously there, but it's the recommendation
8 piece that I'm just trying to understand.

9 MEMBER PI-SUNYER: Well, I think
10 the recommendations are the IOM
11 recommendations, and I think, you know, they
12 had a task force who did a very good job in
13 looking at the issue, and I think the message,
14 as Rafael said and as Christine said, needs to
15 get back to the obstetricians who, you know,
16 are not doing this.

17 I can tell you we deliver more
18 babies than anybody else in New York, and for
19 a lot of them there isn't the time or the
20 energy to talk about weight very much.

21 CHAIRPERSON VAN HORN: I think the
22 other thing, I actually attended the IOM

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1 meeting where a lot of this was discussed, and
2 I think there are actually two very important
3 issues that relate to our work, and it's not
4 the obstetricians. It's the gynecologists. I
5 mean, we're talking about primary prevention
6 here, and as Rafael so eloquently stated, the
7 fact is that this needs to happen before a
8 woman gets pregnant in terms of recognizing
9 the need for weight control early on and
10 establishing a life style that is consistent
11 with the kinds of recommendations that we're
12 making.

13 I would also suggest that by
14 providing a mother-to-be with healthful
15 lifestyle intervention early, that can have
16 tremendous benefits and payoffs in terms of
17 the family she's about to raise.

18 So I think this is all an area
19 based on, again, slowly but consistently
20 acquired data that we're now beginning to
21 address that hasn't been previously available
22 to this committee, that we now need to embrace

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1 and make recommendations about collecting
2 additional data so that we know specifically
3 how to make those recommendations.

4 Tom.

5 MEMBER PEARSON: You know, I'd
6 just like to ask about this tradeoff issue.
7 Obviously the issue is this tremendous inter-
8 individual heterogeneity in weight gain, and
9 certainly there has been a lot done on the
10 genetics side with A25T polymorphisms, and
11 clearly there are some women, there's a
12 subgroup here that are really very much
13 predisposed.

14 And it seemed to me from my look
15 at that literature that the most effective
16 interventions in them was physical activity.
17 This issue of the tradeoff, certainly with the
18 fatty acid group we're going to have some
19 comments on DHA, and those are not going to be
20 reduce those nutrients. It's going to be to
21 increase them.

22 So we're going to be at cross-

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1 purposes here unless we come up with a strong
2 message. I think that strong message has to
3 do with caloric expenditure side of this has
4 better tradeoffs than the nutrient side.

5 I would just comment on that.

6 MEMBER NELSON: This is Mim
7 Nelson.

8 Back, Larry, thinking about your
9 question because I actually was thinking about
10 that yesterday after we had our subcommittee
11 meeting and wondering so where does this fit
12 because it could be considered a non sequitur
13 a tiny bit.

14 But I think if we have a section
15 in the report about, you know, healthy
16 weights, different categories and healthy
17 weight through different, you know, life
18 stages, I think that it's more not a
19 recommendation. It's more just sort of
20 stating what's out there. I would assume
21 that's sort of where this would be.

22 But a follow-up question, Rafael.

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1 Did the committee have any guidance on
2 postpartum weight loss? None. Because that
3 to me seems to be where we may -- I don't know
4 -- but this is where the big issue is. If
5 they don't lose the weight between
6 pregnancies, they just keep ratcheting up, and
7 I think that that's a -- you know this area
8 better than I do.

9 MEMBER PEREZ-ESCAMILLA: I mean,
10 the committee fully acknowledged that they
11 want to deal with this hopefully before
12 pregnancy if it didn't work between
13 pregnancies, but how to actually get to it,
14 there are a couple of ongoing randomized
15 trials looking at, you know, weight loss
16 interventions after the delivery of babies.

17 By the way, almost all of the
18 evidence that we had was observational. Very,
19 very little experimental.

20 MEMBER NELSON: But doesn't ACOG
21 or others have some guidance on the sort of
22 rate of weight loss or guidance on -- no?

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1 Nobody has any sort of guidance on weight,
2 returning to pre-pregnancy weight?

3 MEMBER PEREZ-ESCAMILLA: Like how
4 fast and how you get --

5 MEMBER NELSON: Yeah. No?

6 MEMBER PEREZ-ESCAMILLA: -- to
7 that point as far as -- I'm not aware of that.

8 MEMBER NELSON: Okay.

9 MEMBER PEREZ-ESCAMILLA: Yeah.

10 MEMBER SLAVIN: I want to just
11 make one comment and it has to do with -- this
12 is Joanne here -- with low birth weight babies
13 and, you know, like the concern of your
14 committee that if we talk about too much
15 weight reduction, a lot of people that go into
16 pregnancy are on really poor diets. So even
17 though they're obese, they have low protein
18 intakes, and their diets are poor.

19 So balancing that, because it is
20 that with the number of low birth weight
21 babies in the U.S., we have a huge problem
22 with not delivering healthy babies despite

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1 this obesity issue. And I know that was a
2 frustration of your committee.

3 MEMBER PEREZ-ESCAMILLA: And I
4 think the committee, you know, felt very
5 strongly that providing access to registered
6 dietitians and appropriate nutritional
7 counseling is crucial for making this work
8 exactly for the point that you are raising.

9 CHAIRPERSON VAN HORN: And just to
10 reiterate what Rafael said about the
11 randomized controlled trials, I'm aware that
12 as we speak there are several that are now
13 beginning to address that issue. However,
14 they state categorically that the data
15 collection stops at the time of birth.

16 So where we need to provide some
17 additional interface, I think, is between that
18 very crucial time of delivery and then
19 initiation of a family and that kind of
20 counseling to encourage life style related to
21 family oriented eating and activity behavior
22 is certainly not addressed adequately.

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1 MEMBER PEREZ-ESCAMILLA: And I
2 thoroughly agree, and also it's an issue of
3 access, counseling and providing the access to
4 different groups, to the foods and the
5 physical activity opportunities that they
6 need.

7 MEMBER NICKOLS-RICHARDSON: And
8 this is Shelly. I just want to comment that I
9 think it's very important to have this in the
10 report, in the technical report, because the
11 CNPP over the last several years has done an
12 excellent job of putting together the My
13 Pyramid for Moms, and we need to have
14 something scientifically that justifies where
15 those recommendations come from, along with
16 the IOM recommendations for pregnancy and
17 lactation.

18 CHAIRPERSON VAN HORN: And then
19 one final point, and that is about breast
20 feeding. I think that, you know, there is now
21 growing evidence to suggest that, you know,
22 breast feeding is just a really good thing to

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1 feed children. How about that? And the
2 longer the better, and it has implications not
3 only for nutrient adequacy, but also for
4 weight control, et cetera, in the mom.

5 So I think this report, again,
6 will be one of those that encourages, you
7 know, not only breast feeding as an ideal
8 source of nutrition for infants, but the
9 research recommendations that will accompany
10 this report related to that, I think, also
11 will continue to support data collection on
12 that topic.

13 MEMBER PEREZ-ESCAMILLA: And our
14 subcommittee will summarize the systematic
15 reviews that have looked at breast feeding and
16 maternal weight loss.

17 MEMBER PI-SUNYER: Okay. We're
18 going to move on to our last speaker. Mim
19 Nelson is going to talk about physical
20 activity.

21 MEMBER NELSON: Thank you, Xav.

22 So just a little bit of context.

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1 In the 2005 Dietary Guidelines there is
2 discussion around physical activity related to
3 health and body weight, and since that time
4 we've had the 2008 Physical Activity
5 Guidelines for Americans, but we still felt as
6 a committee that it was important that, just
7 as we did actually in the physical activity
8 guidelines -- I was part of that committee --
9 we talk about the importance of nutrition, but
10 basically link it to the dietary guidelines.

11 We thought in the dietary
12 guidelines we, again, need to not necessarily
13 revisit all the work that the physical
14 activity guidelines committee did, but that to
15 make reference to it and bring the sort of
16 high level recommendations and guidance from
17 those guidelines into the dietary guidelines.

18 So the main question we have here
19 is how is physical activity related to body
20 weight and other nutrition related aspects of
21 health. In particular, how much physical
22 activity is needed to maintain a healthy body

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1 weight, lose body weight if overweight or
2 obese and avoid regain in weight reduced
3 persons.

4 So we really have two questions,
5 one question that has three subcomponents.

6 So just a little bit of background
7 for those that aren't as familiar. In 2008,
8 the inaugural physical activity guidelines for
9 Americans were released by the U.S. Department
10 of Health and Human Services. I really have a
11 large nod to my right, to Penny Slade-Sawyer
12 who is at the table here, who was incredibly
13 instrumental in not only putting that
14 committee together, but seeing it through to
15 the end. So I really appreciate all of
16 Penny's guidance.

17 So similar to the dietary
18 guidelines, the development of the physical
19 activity guidelines resulted from the evidence
20 provided in the Physical Activity Guidelines
21 Advisory Committee report released in May of
22 2008. It was a 683 page technical report, and

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1 I think our committee may be well on our way
2 to doing another 600 page technical report if
3 we're not careful.

4 So if we had had more time, it
5 would have been half the length. So Part G,
6 Section 4 of the report focuses on physical
7 activity and energy balance. Other sections
8 of the report focus on all cause mortality,
9 cardiorespiratory health, metabolic health,
10 musculoskeletal and functional health, cancer,
11 mental health, and adverse events.

12 In addition, the report provided
13 evidence regarding physical activity for under
14 represented groups, including youth, pregnant
15 and postpartum women, persons with
16 disabilities, and racial and ethnically
17 diverse populations.

18 Because the physical activity
19 guidelines advisory committee report was
20 guided by 13 physical activity experts and is
21 recent, systematic and thorough, the 2010
22 dietary guidelines committee felt it was

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1 prudent to use the report for the evidence to
2 answer these couple of questions.

3 So that just sort of gives you
4 some of the context. So our source of
5 evidence, in short, is the 2008 Physical
6 Activity Guidelines Advisory Committee report
7 that was submitted last year.

8 So how is physical activity
9 related to body weight and other nutrition
10 related aspects of health? There is clear and
11 consistent evidence that physical activity or
12 physically active people have higher levels of
13 health related fitness, a lower risk profile
14 for developing most chronic disabling medical
15 conditions, and lower rates of various chronic
16 diseases than do people who are inactive.

17 Physically active people are at a
18 reduced risk of becoming overweight or obese,
19 and I think very important, since two-thirds
20 of the population is already obese or
21 overweight, adults of all body weight
22 classifications gain health and fitness

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1 benefits by being habitually physically
2 active. This is very important.

3 There was another point. I should
4 also note what I didn't, but I will in the
5 actual writing of the report or section here,
6 is that by objective measures, less than
7 probably ten percent of children are meeting
8 guidelines and probably only about five
9 percent of adults are meeting guidelines when
10 you use objective measurements for looking at
11 the previous guidelines.

12 So we have a very large percentage
13 of the population, somewhere in the vicinity
14 of 80 to 90 percent, who are not physically
15 active, and I would say the most important is
16 that it's not about leisure physical activity.
17 It's about increased sedentary time,
18 decreasing activities related to commuting,
19 self-ambulation, you know, getting out there,
20 just taking a walk, decreases in how we work.
21 Very few of us now do manual labor. Actually
22 leisure activity stayed just about the same

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1 over the time, but we have become more
2 sedentary because of all the different
3 components of total energy expenditure. So
4 just, again, as a framing.

5 So the guidelines, if I could, we
6 will bring these guidelines and place them in
7 the dietary guidelines so that we have them
8 and that we can cross-reference, but for
9 children, overall 60 minutes or more of
10 physical activity daily, aerobic activity.
11 Most of the 60 minutes should be either
12 moderate or vigorous intensity aerobic
13 activity and should include vigorous intensity
14 physical activity at least three days per
15 week.

16 As part of the 60 minutes,
17 children and adolescents should include muscle
18 strengthening and bone strengthening physical
19 activity on at least three days per week.

20 For adults, all adults should
21 avoid inactivity. That's probably the most
22 important guidelines. Some physical activity

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1 is better than none. For substantial health
2 benefits, adults should do at least 150
3 minutes of moderate intensity physical
4 activity or 75 minutes of vigorous intensity
5 activity or an equivalent combination of the
6 two. For additional health benefits,
7 increased aerobic activities at 300 minutes
8 per week of moderate physical activity or 150
9 minutes of vigorous physical activity or an
10 equivalent combination of the two. And adults
11 should be doing two muscle strengthening
12 activities on two or more days a week.

13 Some stuff that I would note which
14 you don't see is that we're not talking about
15 every day. We're not giving, you know, that
16 it should be 20 minutes or 30 minutes;
17 basically saying that it's a weekly goal. So,
18 in fact, I think what's important here is that
19 there's a lot more flexibility; that people
20 can actually do this on a weekend. I don't
21 mean to advocate weekend warrior, but for
22 those of us that are sitting all day here

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1 today for ten hours, but, yes, we have to be
2 careful from an injury prevention, but there
3 are many different ways to actually meet these
4 goals.

5 Certainly the more vigorous that
6 you participate, the higher the intensity, the
7 fewer number of minutes.

8 And then for older adults, to
9 follow the adult guidelines that I just went
10 over, and when older adults cannot meet those
11 adult guidelines they should be as physically
12 active as their abilities and conditions will
13 allow.

14 In addition, adults who are at
15 risk for falls should do exercises that
16 maintain or improve balance.

17 So how much physical activity is
18 needed to maintain a healthy body weight?
19 There's clear and consistent evidence that
20 physical activity provides benefit for weight
21 stability. Looking at weight stability over
22 decades is very difficult. These kinds of

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1 trials are really much more observational. We
2 will never have an RCT that looks over decades
3 and looks at weight gain. We're looking at no
4 change in body weight here.

5 So for children basically we're
6 following -- we came up with a recommendation
7 to follow the main guidelines, 150 minutes to
8 300 minutes for moderate intensity or the
9 equivalent, 75 to 150 minutes of vigorous or
10 an equivalent of the two.

11 And we also note that there is a
12 great deal of inter-individual variability
13 with physical activity and weight stability.
14 Some adults may need more to maintain body
15 weight, but I think most important is that
16 achieving energy balance and a healthy weight
17 depends on both energy intake and expenditure.
18 You cannot talk about weight stability, weight
19 loss or weight stability after weight loss
20 without talking about energy intake.

21 Looking at how much physical
22 activity is needed to lose weight if

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1 overweight or obese, the reality is that if
2 you take someone and you put them in a
3 metabolic unit and you control their dietary
4 intake exquisitely and you increase their
5 physical activity, you can get them to lose
6 weight.

7 That doesn't happen in the real
8 world. People compensate with appetite
9 increase, and even though they may feel like
10 they're keeping the energy intake stable, they
11 aren't. So theoretically physical activity
12 itself works, large doses for weight loss, but
13 in reality you need to combine the two. But
14 there is clear and consistent research that
15 shows that a large dose of physical activity
16 is needed for substantial weight loss.

17 Adults who are most successful
18 achieving weight loss combine calorie
19 restriction with increased physical activity
20 participation. I will also note that the body
21 composition changes when you combine physical
22 activity with energy restriction, are more

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1 positive towards preserving lean tissue and
2 losing more body fat, and that a combination
3 of caloric restriction, again, at the 150 to
4 300 minute of moderate intensity or 75 to 150
5 minute or an equivalent combination of the two
6 is recommended, but more may be needed to
7 achieve substantial weight loss. So it's
8 really in combination with energy restriction.

9 In terms of how much physical
10 activity is needed to avoid regain in weight
11 reduced persons, limited evidence for the
12 effectiveness of physical activity alone in
13 preventing weight regain following substantial
14 weight loss. Adults who were successful at
15 long-term weight maintenance following weight
16 loss appear to limit caloric intake in
17 addition to maintaining a high level of
18 physical activity.

19 The data is fairly strong that to
20 prevent substantial weight gain over six
21 months, adults may need more than 300 minutes
22 of moderate or 150 minutes of vigorous

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1 activity or an equivalent combination of the
2 two.

3 There is no doubt, and I think
4 there is emerging evidence that, you know,
5 people who have lost weight and are trying to
6 maintain that weight loss over time. They
7 need to be more vigilant about energy intake
8 and physical activity, and we may in the
9 report talk a little bit about some of the
10 new, emerging data, you know, on how that
11 their energy needs may actually be different
12 after weight loss than before weight loss for
13 an equivalent body weight and composition.

14 So I'm trying to think of other
15 things that are important here. I think the
16 main sort of message here is that inactivity
17 is the most risky thing you can do; that some
18 activity is better than none; more is better;
19 and that physical activity is important when
20 you're talking about weight stability, weight
21 loss, and weight maintenance after weight
22 loss, but it needs to be done in combination

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1 with energy restriction.

2 I think that was it. I'm happy to
3 take questions at this point in time.

4 One other piece. We talked in our
5 subcommittee meeting that we are going to do
6 -- because this is really about energy
7 expenditure -- we are going to be looking at
8 the 2005 report. We're going to be updating
9 sections around caloric intake, and actually
10 it's sort of in different places, and we
11 realized as we were talking yesterday there
12 needs to be an equivalent one section in this
13 part of the report, probably close to this I'm
14 hopeful, that really talks about energy intake
15 itself and requirements and suggestions, et
16 cetera.

17 So we're going to balance this
18 with energy intake.

19 MEMBER PI-SUNYER: Thank you, Mim.

20 Questions or comments? Eric.

21 MEMBER RIMM: This is Eric Rimm.

22 That was very nice, Mim. Thank

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1 you. It's nice that you had your own IOM
2 report to fall back on, too. It really makes
3 such an exquisite presentation. I notice
4 Rafael had the same thing. It's really nice
5 when they put together 15 experts to answer
6 one question.

7 MEMBER NELSON: Whoa. We had
8 about 60 questions we were answering. Just so
9 you know, it was done exactly like the
10 physical --

11 MEMBER RIMM: It's spectacular
12 that you have such very nicely articulated the
13 issue with physical activity, and the issue
14 that is not physical activity alone, that
15 there is a fair bit around caloric
16 restriction.

17 I wonder. It made me think of
18 Rafael's comment about food patterns as
19 opposed to individual components of the diet
20 that are important, and I wonder if you really
21 are sort of defining what is physical activity
22 pattern or energy expenditure pattern; that

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1 the part that is not as well documented is the
2 sedentary activity aspect of it.

3 I know there's a huge literature
4 on television watching, especially among kids,
5 and how that leads to obesity. Is there a
6 possibility that we can include something that
7 better defines what sedentary is, that we
8 could come up with a recommendation that sort
9 of talks about not just doing physical
10 activity, but not doing extreme sedentary
11 activity?

12 MEMBER NELSON: Yes. This is Mim
13 again.

14 In another question that we are
15 going to be addressing between now and
16 February is going to be more around behavior
17 and how that relates to adiposity and body
18 weight. We're going to be dealing with screen
19 time, television viewing, things like the
20 family meal. I mean a whole bunch of things
21 that actually influence both energy intake and
22 energy expenditure.

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1 So I think we'll be doing it
2 there. I mean, I look at Penny, but I think
3 that it will be appropriate for us, and maybe
4 you can voice your opinion, too, but I really
5 hope that we can really tie these two
6 different reports together because in the
7 physical activity, the actual guidelines, not
8 the report, to your question, Eric, there are
9 so many different ways that we show how you
10 can meet the physical activity guidelines. You
11 know, you don't even need to put your sneakers
12 on kind of; that you can build it into your
13 lifestyle. You can do more vigorous activity.

14 I mean, there is sort of the range, and we
15 also talk about limiting sedentary time.

16 But I think we'll be doing that
17 more when we talk about the -- yes, I know.
18 Oh, yes, I got another note. Okay.

19 The only thing that I will say in
20 terms of flexibility is that we did talk in
21 the committee that when we're talking about
22 physical activity, you get to count it towards

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1 the guidelines if it's a bout of ten minutes
2 or more. So there wasn't much evidence less
3 than that.

4 MEMBER PI-SUNYER: Yes, I think
5 Eric's point is very well taken. I mean, the
6 recent report that the TV viewing of children
7 is still going up; it hasn't plateaued. So
8 it's still going the wrong way. So it's
9 crucial, I think.

10 MEMBER PEREZ-ESCAMILLA: This is
11 Rafael.

12 I just want to mention that
13 television viewing is not only an indicator of
14 sedentary zone, but also of exposure to
15 marketing of junk food.

16 MEMBER NELSON: Marketing the junk
17 food and a place to eat.

18 MEMBER PEREZ-ESCAMILLA: And a
19 place to eat.

20 MEMBER NELSON: Yeah, and I think
21 between Christine and myself, we're going to
22 be dealing with behavior quite a bit in that

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1 range.

2 MEMBER WILLIAMS: I had one
3 comment about the recommendation for children.
4 I think in some ways we need to separate out
5 children in different age groups. For
6 example, with preschool children, a lot of
7 whom are in nursery schools and day care, that
8 we need a little more attention to structured
9 physical activity. There's often an idea that
10 just let them go out and play and that will be
11 adequate, and often there are children that
12 sit on the side and don't participate and
13 others that do.

14 And also, with young children we
15 need to pay a little more attention to
16 practicing motor skills because those skills
17 are important to achieve in preschool. Those
18 are the children that will like to play sports
19 if they can catch a ball and kick and balance.

20 So there are different things for
21 different age groups that are important.

22 MEMBER NELSON: Yeah, and I didn't

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1 put the full guidelines in there, but one of
2 the main things is that the activities are age
3 appropriate, that they're fun, and that when
4 you add in the bone and musculoskeletal
5 activities, you get much more of the growth
6 and development and coordination activities.

7 The data at least from Rick
8 Troiano and his group looking at accelerometer
9 data, I'm not looking before age six, but the
10 six to 12 year olds actually are the only
11 group that sort of meet the guidelines because
12 of play. And I would argue that we need to
13 actually engineer more play into our
14 children's lives just for the sake of play
15 because that will do a much better job of
16 socializing them and having a higher energy
17 expenditure.

18 MEMBER CLEMENS: Rog here. Thank
19 you so much.

20 Can we have some more play in this
21 group as well?

22 (Laughter.)

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1 MEMBER CLEMENS: In a serious note
2 -- and perhaps that could be serious -- we see
3 that across the country many school districts
4 are, in fact, cutting play time and despite
5 the need to address the comment that Linda
6 made earlier about childhood obesity, as a
7 result they think they need more class time.

8 My fear, and you've experienced
9 this, is, well, because we're having less play
10 time we have a Vitamin D issue as provided by
11 a committee. We have an obesity issue coming
12 out. So actually what we have in school
13 systems for economy reasons are actually
14 exacerbating the condition called ill health
15 amongst our children.

16 MEMBER NELSON: I completely
17 agree. It might be beyond the scope of this
18 committee right now, but I think that the
19 greatest -- the interesting stuff when you
20 look at children's days, the greatest amount
21 of physical activity even for those children
22 that don't commute by walking or don't get to

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1 school by walking, it's before school and just
2 after school, and we need to do better with
3 the before school and after also.

4 And you know, I'm thinking of my
5 colleague Christine Economos who has done so
6 much with curriculum within schools, but still
7 meeting, you know, the educational goals, and
8 there's lots of ways with little children to
9 have physically active activities that relate
10 to math and reading and geography and
11 everything else.

12 And I think PE is one that I'm
13 less excited about PE as I'm thinking of the
14 whole day of the child.

15 RADM SLADE-SAWYER: This is Penny
16 Slade-Sawyer.

17 And I just might add here that
18 there is emerging research on sedentary
19 behavior itself separate and apart from the
20 research going on on physical activity and the
21 dose required for this or that. The early
22 evidence is that sedentary behavior in and of

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1 itself is not a good thing. So that merely
2 getting up and walking around during a long
3 meeting --

4 (Laughter.)

5 RADM SLADE-SAWYER: -- or even
6 standing at your chair for a couple of minutes
7 may enhance health.

8 Of course, that's very
9 preliminary, but I'm hoping that we will be
10 able to report convening a group like
11 yourselves around the science of physical
12 activity in five years or more, and then have
13 an update then on the science relating
14 physical activity to health.

15 Another thing I want to add is
16 that separate from the work that this group is
17 doing I think neither message is as powerful
18 as it can be. In other words, together the
19 energy balance, the calories in, the calories
20 out are crucial, and I see these two sets of
21 guidelines as inseparable really.

22 And one should certainly within

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1 reason support the other. The physical
2 activity experts were not nutrition experts,
3 and so we did not delve into the details. Mim
4 was on that, and we were delighted that she
5 could come from that group to this one. We
6 hope that one of you with some physical
7 activity expertise perhaps can serve on the
8 next guidelines for physical activity, but
9 these things are hooked together.

10 MEMBER PI-SUNYER: Rafael.

11 MEMBER PEREZ-ESCAMILLA: The data
12 for low income Latinas, what it shows is that
13 they have higher levels of occupational
14 physical activity but lower levels and
15 extremely low levels of recreational physical
16 activity.

17 And the question that has been
18 asked to me several times is are they the same
19 or are these jobs so stressful that it
20 mitigates the possible benefits for physical
21 activity.

22 MEMBER NELSON: Well, the

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1 occupational data -- this is Mim Nelson -- is
2 pretty strong. People that are physically
3 active in their occupations actually do better
4 than their same counterpart, same ethnicity,
5 et cetera, income level that are in a job
6 that's very sedentary. So those people
7 generally do better across the board.

8 We didn't look at the stress
9 piece, although we know that people who are
10 physically active generally have reduced
11 stress responses, but we didn't look at that
12 in particular with different ethnic minority
13 groups.

14 But I think that, you know, the
15 reality is even if you look at those
16 occupational -- people who have for an
17 occupation physically active jobs, when you're
18 looking at low income, regardless of
19 ethnicity, they are still very overweight. So
20 the energy intake piece is just a big sledge
21 hammer here, the intake piece.

22 And, yes, the expenditure is

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1 important, but I think when you're talking
2 about weight, I'm going to throw out a number,
3 but we're talking about 75 percent of the
4 contributions are probably around intake and
5 maybe 25 around expenditure, but we are such a
6 sedentary society that, you know, if we were
7 all out being active for ten hours a day
8 instead of sitting, we might be looking at
9 this differently.

10 CHAIRPERSON VAN HORN: I want to
11 share with the group an unintended consequence
12 of having moved my office last week and
13 exactly this issue, and here it is. Again, I
14 mentioned earlier about American ingenuity. I
15 now work in a smart room. So when I walk in
16 the room the light goes on, and I was sitting
17 at my computer as I always do -- and I bet you
18 can relate -- for a long time working away,
19 and suddenly the light went off.

20 (Laughter.)

21 CHAIRPERSON VAN HORN: And I
22 realized, oh, I guess I haven't been moving,

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1 and so I'm just suggesting that, again,
2 environmentally there are some of these kinds
3 of approaches that could be quite effective in
4 getting us up and moving around, and I bet
5 there are, again, people out there that can
6 think of lots of creative ways to keep us
7 moving.

8 So, Larry, did you --

9 MEMBER NELSON: Well, if I could
10 just have one final comment.

11 CHAIRPERSON VAN HORN: Yes.

12 MEMBER PI-SUNYER: Do you have
13 another slide?

14 MEMBER NELSON: No, I don't. Well,
15 it's there, but the last thing I would say, I
16 think the greatest way from a public health
17 standpoint that we can get people more active
18 is actually through the built environment and
19 through a systems approach, not by telling
20 people you need to exercise more. It's going
21 to be through commuting, you know, access,
22 connectivity of communities, sidewalks, et

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1 cetera. That's where all of the best research
2 is in terms of a public health.

3 So there you go. There's your
4 last slide. Do you want to finish with this
5 or do you want me to finish with this?

6 I can because it's mostly what
7 Christine is going to.

8 So finally, as a committee, what
9 we're going to be working on for the remainder
10 of our work is looking at macro nutrient
11 proportions and energy intake, looking at
12 childhood overweight and obesity, additional
13 topics that Christine hasn't already talked
14 about.

15 And I will say a big nod to
16 Christine. She has done this childhood
17 obesity work so well, as has everybody, but it
18 has really been thorough.

19 Both Christine and I are going to
20 be looking at dietary behaviors with children
21 and adults. We're going to be looking at
22 environmental factors, the food environment,

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1 et cetera, and then some different population
2 subgroups, and that's it.

3 Thank you.

4 MEMBER PI-SUNYER: Good. Any
5 other comments or questions?

6 MEMBER FUKAGAWA: I have one last
7 question.

8 MEMBER PI-SUNYER: Yes.

9 MEMBER FUKAGAWA: One of the
10 concerns that oftentimes schools are facing in
11 preschools are issues of, quotes, overactive
12 children, and so many of their efforts are,
13 you know, designating that they're not normal.
14 You know, I just wonder is there evidence to
15 show that perhaps, you know, hyperactive kids
16 are better at maintaining their weight? And
17 you know, what balance could we strike for
18 something like that?

19 MEMBER WILLIAMS: That's a very
20 difficult question because often the
21 overweight children are put on stimulants that
22 affect their appetite, but I know there is

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1 some data with preschool children that when
2 they're actually in the preschool, they're
3 actually less active because they're always
4 saying, "Sit down and be quiet."

5 So preschools do have a need for
6 structured physical activity programs and to
7 promote that, but unfortunately a lot of
8 preschools don't have the space. Many of them
9 don't have an adequate play area. It's a
10 difficult question.

11 But I don't think there are any
12 studies of active children, very active
13 children followed for a period of time and
14 looking at weight, active children who haven't
15 been medicated.

16 MEMBER NELSON: But to that end,
17 and this is, again, you know, work from my
18 colleague Chris Economos and others, but you
19 know, if we could get children more active, I
20 mean, the data is pretty strong about the
21 behaviors in the class are much better if they
22 can be more active.

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1 I mean, some school districts are
2 doing a better job with, you know, standing
3 desks and having places so that the children
4 can move and not have to be seated all the
5 time, and I really applaud these efforts
6 because I think the children, being a mother
7 of a son who is incredibly active, you know,
8 where a school just stifled him terribly,
9 couldn't learn that way, you know, I think
10 that the school districts that are embracing
11 this sort of different learning styles,
12 allowing children to be more active is really
13 a good way to go.

14 MEMBER WILLIAMS: This is
15 Christine again.

16 There are programs. For example,
17 the ILSI program Take Ten where you actually
18 try to incorporate ten minutes of play time,
19 active play, into the classroom as a reward
20 for finishing their homework and doing their
21 work, and I think approaches like that have a
22 lot of promise for increasing the total amount

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1 of physical activity during the day for school
2 children.

3 MEMBER NELSON: I just can't help
4 it because the schools, we're doing so much in
5 that area. The other thing is, you know,
6 there are still many school districts that
7 punish children by not allowing them to go out
8 to recess, and that has got to stop, or punish
9 them, you know, either food or physical
10 activity. You cannot have these punishments.

11 And along those lines, we also
12 have to get schools with -- you know, the bake
13 sales are five days a week, and what they're
14 selling for foods, I mean, there's a whole --
15 the energy intake and the energy expenditure
16 piece is a real issue. So this penalizing
17 students by not allowing them play is
18 terrible.

19 MEMBER APPEL: This is Larry
20 Appel.

21 I had a question for you, getting
22 back to your presentation, and a difference

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1 between 2005 recommendations and now for the
2 amount of physical activity for weight regain.
3 I think I was on the energy balance
4 subcommittee at that time, and it was viewed
5 as not great data, but we said we had a huge
6 number, 60 to 90 minutes per day to avoid
7 regain.

8 So in terms of, you know, this
9 will be a big change, the 300, and I think we
10 felt, you know, there were practical issues
11 about that number, but that was the best
12 number we had.

13 Was there a change in the evidence
14 or is it basically an interpretation? I
15 mean, what's the reason that --

16 MEMBER NELSON: Some was an
17 approach, I think, and I wasn't on the 2005
18 guidelines or the IOM report that had come out
19 shortly before that, but we looked less at the
20 doubly labeled water data because it was much
21 more theoretical than it necessarily was
22 practical, and in fact, the regain is over 300

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1 minutes a week. We're talking about for how
2 much to avoid regain. We're still advocating
3 more than 300 minutes.

4 So you're saying that because it's
5 higher we're talking about --

6 MEMBER APPEL: Well, it's lower.

7 MEMBER NELSON: Lower. It was 60
8 to 90 before.

9 RADM SLADE-SAWYER: Can I speak to
10 that? I think that what we did last time was
11 quantify it in a more specific way. This one
12 says adults may need more than 300 minutes a
13 week, and if you think of 60 minutes five days
14 a week, that's about 300 minutes, and we
15 quantified 60 to 90, and I think this
16 committee felt that we did not state that
17 well.

18 And that was not in the scientific
19 report. That was our fault. In other words,
20 that was the writers of the guideline.

21 Kathryn.

22 MS. McMURRY: Yes, just to

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1 elaborate a bit, I believe the amount of
2 physical activity -- Kathryn McMurry -- in
3 the 2005 report was based primarily on the
4 weight control registry, following people who
5 had lost weight.

6 MEMBER NELSON: The other is that
7 I think that there wasn't as much emphasis on
8 energy intake, and the data is pretty strong
9 that for weight regain in particular, the
10 energy restriction is very important.

11 CHAIRPERSON VAN HORN: Okay. We
12 will eliminate our sedentary behavior for 15
13 minutes. So please take a break.

14 (Whereupon, the foregoing matter
15 went off the record at 10:51 a.m.
16 and went back on the record at
17 11:07 p.m.)

18 CHAIRPERSON VAN HORN: Welcome
19 back, everyone. I hope you've had a workout
20 and now you're ready to be seated and listen
21 for the next subcommittee, which is chaired by
22 Roger Clemens and also Rafael.

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1 So take it away, Roger.

2 MEMBER CLEMENS: It's always
3 exciting to talk about food safety just before
4 lunch.

5 (Laughter.)

6 MEMBER CLEMENS: Thank you very
7 much, Linda, for the comments.

8 First of all, I'd like to thank
9 very much our wonderful staff, Kellie, Donna,
10 Holly, Shirley, without whose assistance and
11 guidance this would not happen.

12 I also want to thank the hundreds
13 of consumers who provided wonderful insights
14 and comments relative to the items that Rafael
15 and I will discuss today.

16 With that, there are several items
17 that will have undergone extensive review.

18 Rafael will address those items in
19 the next few moments. There are other items
20 that will not undergo extensive review as we
21 discussed.

22 They will be topics that were not

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1 addressed in the last Dietary Guidelines, and
2 I will address those at the next meeting.

3 So that having said that, Rafael
4 will address right now in-home practices, as
5 well as the ever popular topic of methyl
6 mercury in fish.

7 So, Rafael, it's all yours. Thank
8 you.

9 MEMBER PEREZ-ESCAMILLA: Thank you
10 very much, Roger.

11 And I want to echo my personal
12 thanks as well to the wonderful staff from
13 USDA and the Department of Health and Human
14 Services that have supported us in many ways.

15 So to what extent do consumers
16 follow proper techniques for food storage,
17 preparation, and handling at home? Background
18 information, foodborne illnesses represent a
19 serious morbidity burden in the country, and
20 they are responsible for over 5,000 deaths per
21 year with a substantial cost to society. The
22 proportion of outbreaks that can be attributed

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1 to safety practices at home remains unknown,
2 although it is believed to be substantial.

3 An indirect way of assessing this
4 risk is by documenting consumers' food safety
5 practices at home. The review was based on
6 the following criteria: peer reviewed
7 articles published between June 2004 and March
8 2009 among individuals two years old or older,
9 and we targeted both healthy as well as
10 population at higher risk, and the exclusion
11 criteria was the one that has been defined by
12 the Dietary Guidelines Advisory Committee.

13 The question is: to what extent
14 do consumers follow proper techniques for food
15 storage preparation and handling?

16 And the conclusion, the proposed
17 conclusion is that U.S. consumers do not
18 follow proper food storage preparation and
19 cleaning sanitation techniques at home, and
20 this conclusion is supported by strong
21 epidemiological observation and evidence.

22 The implications of this review

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1 are that risky food safety behaviors at home
2 are likely to translate into home based food
3 borne illness outbreaks. Oftentimes consumers
4 are not translating their food safety
5 knowledge into safe practices. A major
6 barrier is consumers' underestimation of the
7 risk for home based foodborne illness outbreak
8 when proper food safety practices are not
9 followed, thus improving not only consumers'
10 knowledge, but also their attitudes and
11 intentions toward reducing home based food
12 safety risks is needed.

13 We identified 20 studies, one
14 meta-analysis, one systematic review, one
15 quasi experimental study, and 17 observational
16 studies as well, and we also worked in close
17 coordination with Amy Lando and her team with
18 regards to secondary analysis of the 2006 FDA
19 FSIS food safety survey, which is nationally
20 representative.

21 And now I'm going to talk about
22 food safety risks at home across the life

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1 cycle. Two studies involving WIC
2 participants, one conducted in Miami and
3 another conducted in 31 different states, have
4 identified a high prevalence of risky
5 behaviors among pregnant women. For example
6 in one study over half of them ate hot dogs or
7 deli meats without reheating them, increasing
8 the risk for listeria, and the same risk is
9 increased by the consumption of soft and blue
10 veined cheeses, which a third of these women
11 in Miami were consuming.

12 The food practices that were less
13 frequently practiced were the use of cooking
14 thermometers, refrigerating foods within two
15 hours after a preparation, and the safe
16 thawing of frozen foods. And both studies
17 underlined the very low use of meat
18 thermometers and the need to improve the
19 proper thawing of frozen foods.

20 For parents like myself that have
21 college students or for college students that
22 are hearing those, you have been identified --

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1 (Laughter.)

2 MEMBER PEREZ-ESCAMILLA: -- as a
3 high risk group with regard to home based food
4 safety practices. A study conducted
5 essentially in the northeast of the U.S. in a
6 laboratory kitchen found that less than half
7 of the students follow proper procedures even
8 though they knew they were being observed, and
9 this was related to cross-contamination,
10 procedures related to hygiene, cooking
11 temperatures, food storage, and the
12 consumption of so-called risky foods, a number
13 of under cooked foods, among other practices.

14 And when the same group of
15 researchers actually went to the homes or the
16 places where the students lived and they
17 actually conducted an audit of their home
18 kitchen, less than 60 percent scored
19 adequately for kitchen appliance cleanliness,
20 and they looked at the microwave oven,
21 dishwasher and can openers as well. Only
22 seven percent had a meat thermometer, and the

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1 frig temperature was well above the
2 recommended 4.4 degrees Celsius.

3 In an online survey of college
4 students nationwide, researchers have found
5 that they do attempt to be likely to consume
6 foods that may increase the risk of foodborne
7 illness, including home made cookie dough
8 which is made with raw eggs. They consume
9 under cooked eggs and also raw sprouts and to
10 a lesser extent, but still 11 percent consumed
11 raw seafood.

12 In a very interesting study by
13 Yarrow and colleagues, they work with U.S.
14 college students who were health and non-
15 health majors. Among the non-health majors
16 the food safety believes knowledge improved
17 after receiving food safety education.
18 However, they still did not improve their food
19 safety practices.

20 The elderly is another group in
21 which there is a lot of interest because there
22 are a number of reasons why they may be at

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1 higher risk for foodborne illness. So in a
2 study with elderly nutrition program clients,
3 22 percent of participants left casseroles
4 standing in the counter for two hours or more.
5 Sixteen percent were unlikely to wash hands
6 before eating, and about a quarter of the non-
7 white older adults would consume meals left
8 outside overnight.

9 A study based on home delivery
10 programs showed that 35 percent of
11 participants kept leftovers. They couldn't
12 finish the whole portion that they were
13 provided with, and only 15 percent ate
14 remaining within two hours. Thirty-eight
15 percent were not consuming the hot meals right
16 away and left it standing on the counter.

17 In a U.S. nationally
18 representative web-based survey by Kosa and
19 colleagues found that only 16 percent of older
20 adults had a frig thermometer at home, and
21 that those living alone were less likely to
22 have refrigerator at a recommended

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1 temperature, and we know that a very high
2 percent of older adults are living alone.

3 In terms of the question about how
4 consumers perceived the risk of foodborne
5 illness outbreaks in their homes, we can say
6 that in general U.S. consumers are aware of
7 the importance of food safety for human
8 health. However, they do not believe that the
9 home kitchen or their home kitchen is an
10 important source of foodborne outbreaks.

11 U.S. consumers report that
12 industry and government and not themselves are
13 the entities that have the most power or
14 ability to make the biggest difference in food
15 safety outcomes.

16 On the one hand, we identified
17 major food safety knowledge gaps among U.S.
18 consumers. For example, they are not aware or
19 lack specific knowledge regarding pathogens,
20 such as listeria and campylobacter. They are
21 not aware of a food vehicles that may contain
22 those pathogens among those that report being

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1 aware of those pathogens.

2 And a very worrisome finding by
3 Dharod and colleagues with low income Latinos
4 is that they have very little awareness of the
5 term "cross-contamination" and those who claim
6 to be aware really don't have an adequate
7 understanding. It's very hard for consumers
8 to understand how the transmission of
9 something that they don't see is happening.
10 And we know based on FightBac!® the importance
11 of cross-contamination prevention as the axis
12 of gravity around which a lot of the education
13 is being provided.

14 A proper cold storage temperatures
15 and refrigerator cleaning are issues where
16 consumers need much more advice and guidance,
17 and I do want to spend a slide on refrigerator
18 cleanliness because we know that it is an
19 issue. The study by Kosa with U.S. adults
20 found that 53 percent had not cleaned their
21 frig at least one month prior to the survey.

22 A study done in Florida and

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1 Tennessee households found that 78 percent
2 reported emptying and cleaning the frig only
3 occasionally or rarely, and another study in
4 Tennessee, households identified klebsiella
5 and enterobacter issues in one-fifth of the
6 refrigerators. They were nonpathogenic
7 species, but they are indicators of lack of
8 sanitation.

9 And what is very worrisome is that
10 multi-drug antibiotic resistance was detected
11 in these species.

12 So on the one hand, consumers
13 don't have knowledge to follow a number of key
14 food safety behaviors, but on the other hand,
15 they do have some knowledge about other
16 recommended behaviors, but they're just not
17 translating this knowledge into practice. So
18 consumers are familiar with, you know, the
19 need for hand sanitation, the use of meat
20 thermometers, but they are just not practicing
21 it, and some others have suggested that these
22 may be related to the "not in my kitchen," the

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1 optimistic bias, that there is no way that a
2 foodborne outbreak could be the result of
3 something that happens in my home, my home
4 kitchen.

5 Also, researchers have suggested
6 that consumers may lack internal locus of
7 control with regards to food safety, as I
8 stated before. A good number of them just
9 believe that it is beyond their hands to make
10 a difference in terms of preventing foodborne
11 illnesses.

12 Who are the individuals consuming
13 or the groups consuming risky foods? By risky
14 foods we mean foods consumed in such a way,
15 such as undercooked, that pose a
16 microbiological hazard for human health.

17 So college students, I have
18 already reported on that, and Patil and
19 colleagues did a meta-analysis including data
20 for U.S. consumers indicating that there may
21 be a gender differential. Men report greater
22 consumption of raw or undercooked food and

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1 women. Likewise higher income groups are more
2 likely than the lower income counterparts to
3 consume these risky foods, and these findings
4 are consistent with the national
5 representative, 2006 FDA FSIS food safety
6 survey, where almost 20 percent of the adults
7 consume raw fish with this behavior being more
8 common among men and respondents that identify
9 themselves as white or Asian versus black or
10 Hispanic.

11 With regards to the influence of
12 socioeconomic status, racial-ethnic status,
13 and gender, you don't get results always in
14 the expected direction, which is very
15 interesting. Higher socioeconomic status has
16 been associated with more food safety
17 knowledge, but oftentimes with worse food
18 safety behaviors like the consumption of risky
19 foods, and in some studies even the use of
20 meat thermometers.

21 Being a member of a racial-ethnic
22 minority group has been associated with better

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1 food safety behaviors, but also with worse
2 food safety behaviors. It depends which are
3 the behaviors that these studies are looking
4 at.

5 And overall, women are more likely
6 than men to report safer food safety behaviors
7 at home, although men are more likely to
8 report using a meat thermometer probably
9 because they are in charge of the grill
10 whenever --

11 (Laughter.)

12 MEMBER PEREZ-ESCAMILLA: -- there
13 is a need.

14 A very important issue in terms of
15 future research is related to the validity of
16 self-reported food safety behaviors, and this
17 is a huge issue with regard to hygiene
18 cleaning behaviors because of the stigma that
19 this question carriers. And researchers like
20 Cates and colleagues and Dharod and colleagues
21 and others have shown that there is a huge
22 differential in terms of what people say they

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1 do in terms of hand washing and the cleaning
2 and sanitation of the kitchen versus what they
3 are actually observed doing.

4 And you often find threefold
5 differences in terms of the percent who are
6 reporting one thing but actually doing another
7 thing.

8 So it is very important to really
9 develop research methodologies that will allow
10 us to improve the validity of the report of
11 food safety behaviors.

12 Now, what this means is that the
13 data that I just showed you is a best case
14 scenario because a lot of that data, not all
15 of it, but a lot of the data like the
16 nationally representative survey is self-
17 reported.

18 MEMBER CLEMENS: Any comments for
19 Rafael's presentation? Yes, Christine.

20 MEMBER WILLIAMS: I have one
21 question about raw fish. I assume you're
22 talking about sushi. And with respect to the

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1 amount of sushi that's consumed in our
2 country, which is probably significant, what
3 is the exact risk?

4 MEMBER PEREZ-ESCAMILLA: Eric is
5 not here. He's the person. Sushi consumption
6 is not --

7 MEMBER CLEMENS: On cue.

8 MEMBER PEREZ-ESCAMILLA: -- in the
9 U.S.

10 MEMBER RIMM: Sorry. This is Eric
11 Rimm. I was up standing around exercising.

12 I can only speak to the benefit. I
13 don't know about the trends in sushi
14 consumption. You know there clearly are
15 trends in fish consumption for tuna and salmon
16 and things like that, but I don't know how
17 much translates into eating it raw versus
18 eating it cooked.

19 MEMBER PI-SUNYER: Don't you think
20 that most people are -- Xavier -- most people
21 are eating sushi out rather than in their
22 homes? So the safety depends a lot on the

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1 restaurant and what they're doing, how long
2 they keep it.

3 MEMBER PEREZ-ESCAMILLA: Yes.

4 MEMBER NELSON: This is Mim
5 Nelson.

6 I have a couple questions because
7 it seems to me one of the real research issue,
8 you know, you put in one of your slides -- you
9 say that risky food safety behaviors at home
10 was likely to, you know, translate into home
11 based foodborne illness. Is there much -- I
12 mean, I don't know this data -- is there much
13 evidence that it actually does?

14 Because you know, you have also
15 the statement that Americans feel like it's
16 more around the industry and government and
17 things like that, and I think it actually
18 would be helpful to know what the
19 contributions are to foodborne problems. Is
20 it more in the home or not? Because if it's
21 not in the home, then I think we have to
22 reinforce the issues, and maybe Rob -- I don't

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1 know -- somebody from USDA knows this maybe
2 better, but that's one question.

3 MEMBER PEREZ-ESCAMILLA: All those
4 conclusions are inferential.

5 MEMBER NELSON: Yes. So I think
6 we have to be --

7 MEMBER PEREZ-ESCAMILLA: So it's a
8 judgment, and that goes to additional research
9 recommendations.

10 MEMBER NELSON: Okay.

11 MEMBER PEREZ-ESCAMILLA: I was
12 asked not to spend a long time on research
13 recommendations, but in terms of surveillance
14 and monitoring, there are enormous gaps in the
15 system in the country, and for home based
16 right now it is impossible to be able to
17 determine a percent. They go oftentimes
18 unreported. Most of what is caught is because
19 it affects a critical mass of people.

20 MEMBER NELSON: Rob?

21 DR. POST: Okay. This is Rob
22 Post.

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1 Well, I had a question that's
2 related, and that is to the extent to which
3 recalls were considered as a way to track
4 exactly what happens in the home because there
5 are an awful lot of recalls that are related
6 to what we're calling consumer handling, you
7 know, picnics, church picnics and that kind of
8 thing also being included here, whether that's
9 any indication and additional evidence to be
10 considered, especially going back five years
11 or even ten years to see a trend developing.

12 That might be a way to get to some
13 measure of what's happening at the consumer
14 level.

15 MEMBER PEREZ-ESCAMILLA: At the
16 same time, your other question is also very
17 important. There are very few studies that
18 have actually used microbial indicators, and I
19 think the future movement in this area is
20 really going inside the households and using
21 microbial indicators to try to characterize
22 better the risk for practices to translate

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1 into actual foodborne illnesses.

2 MEMBER NELSON: The only other
3 follow-up is I think people right now don't
4 cook anymore. I mean, we have become a
5 society that doesn't cook nearly as much as we
6 used to, and the caution I would have is
7 whatever recommendations we come up with, I
8 don't want to get people scared to cook and to
9 prepare home meals, and so, you know, there
10 can't be a fear.

11 We have so much fear stuff out
12 there that you know --

13 MEMBER PEREZ-ESCAMILLA: There is
14 so much emphasis on cooking it the right way
15 that I don't think they want to be scared
16 about cooking.

17 MEMBER NELSON: Exactly. Good
18 because we need more people cooking.

19 MEMBER PEREZ-ESCAMILLA: Cooking
20 and the right way, and it is just real common.
21 I was very surprised, but, you know, we're
22 eating out a lot, but still 95 percent of U.S.

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1 consumers prepare and consume at least one
2 meal per week in their homes, at least one.

3 MEMBER NELSON: A week?

4 MEMBER PEREZ-ESCAMILLA: And they
5 all have refrigerators and they all have
6 stoves or microwave. So you may not cook from
7 scratch things, but there is a lot of contact
8 with food that is handled in the home.

9 And also we need to think about
10 extensions of the home, the car, the picnics.
11 We need to have a broader concept of what the
12 home is and also while traveling as well. It's
13 another issue, yeah.

14 MEMBER PI-SUNYER: The other thing
15 about fear, what about shellfish? I mean, in
16 the eastern coast certainly a lot of people
17 eat raw shellfish, and it's very good. I eat
18 a lot.

19 (Laughter.)

20 MEMBER PI-SUNYER: I mean I don't
21 think you should scare people away from eating
22 clams and mussels and oysters.

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1 MEMBER PEREZ-ESCAMILLA: Well, I
2 guess the concern is transmission of hepatitis
3 and other very serious -- so, it's again the
4 issue that consumers need to know the source.
5 I mean, are they farmed? Are they wild? You
6 know, what is the microbiological quality
7 control?

8 Just as a note, I go to New
9 Orleans to meetings, and in the restaurants
10 where they serve them, in those places in the
11 restrooms they have all these warnings about,
12 you know, eat raw oysters at your own risk. So
13 it's something that it is acknowledged that it
14 poses a risk.

15 How big of a risk I don't think we
16 know. The confidence intervals are very wide.

17 MEMBER WILLIAMS: I just wanted to
18 say that I think you could gather a lot of
19 data from the local health departments where
20 the foodborne illnesses are reported. I
21 served for a number of years as Deputy
22 Commissioner of Health and in charge of

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1 foodborne illnesses, and the vast majority of
2 reports were from fast food restaurants and
3 from picnics and other events like that where
4 the food is not handled properly and not from
5 sushi or shellfish.

6 So I think perhaps CDC would have
7 data on that.

8 MEMBER PEREZ-ESCAMILLA: Well, in
9 terms of recalls, absolutely. We can look at
10 the data, but it's not going necessarily to
11 reflect home based issues. That's the
12 question here, yes.

13 MEMBER PI-SUNYER: They're not
14 going to come to you and report that they're
15 poisoning you.

16 MEMBER NELSON: But understanding
17 where most of the foodborne illnesses are
18 coming from would be, I think, a big step
19 forward. Are they from the home? Are they
20 from the picnic?

21 MEMBER PEREZ-ESCAMILLA: It is
22 incredibly important. The challenge for

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1 coming up with the data is phenomenal. It is
2 not an easy task, but it's a recommendation
3 that we have in there, and it is going to be
4 emphasizing both in the report because we
5 cannot make progress if we don't have that
6 information.

7 Next, well, I think I have good
8 news now for those of you who were concerned
9 about fish and so on.

10 (Laughter.)

11 MEMBER PEREZ-ESCAMILLA: So what
12 are the benefit-risk ratios for different
13 levels and frequencies of seafood consumption?

14 Well, you've seen the following
15 definition of seafood based on the IOM report
16 as finfish, shellfish and mollusks coming from
17 marine and fresh water sources. As
18 background, in 2004 EPA and FDA jointly issued
19 a fish advisory for the country targeting
20 women who they consider at risk, that is,
21 pregnant or who may become pregnant, lactating
22 and young children, and the whole fish

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1 advisory was based on an allowable upper limit
2 of daily intake for .1 micrograms per kilogram
3 per day of methyl mercury. So the methyl
4 mercury concern is what drove this advisory,
5 and the way it was calculated, was from the
6 lower 95 percent confidence interval limit it
7 was identified as increasing the risk for
8 fetal neurological development times a tenfold
9 uncertainty factor.

10 The advisory states that this
11 target group should avoid large predatory fish
12 that has high concentration of methyl mercury
13 because methyl mercury bioaccumulates up the
14 trophic aquatic chain. So they need to avoid
15 shark, swordfish, king mackerel and tile fish,
16 and consume up to 12 ounces per week of a
17 variety of cooked seafood lower in methyl
18 mercury, limited consumption of albacore white
19 tuna to six ounces per week, and always to
20 consult local advisories for locally caught
21 fresh water fish. And, again, the target
22 group was very clearly defined for this

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1 advisory.

2 Why do we have to revisit this
3 question, as it was addressed in the 2005
4 Dietary Guidelines Advisory Committee report?
5 Well, there is still uncertainty about risks
6 previously assumed. There is no existing
7 recommendation for groups not targeted by the
8 2004 fish advisory, and most importantly, the
9 public at large is very confused, and we can
10 see that in the media. An article, I think,
11 was December in the New York Times that went
12 back again to ask what are we doing. People
13 are fused confused, and also health care
14 providers specifically, OB-GYNs, for example,
15 advising women during pregnancy not to eat
16 fish at all. That has never been the intent
17 of this recommendation.

18 We included studies published
19 between June 2007 and until now. Two years
20 old and older were included, and we looked for
21 studies dealing with healthy as well as
22 special populations, and a very important

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1 piece of evidence, the systematic review by
2 Mozaffarian and Rimm, which was published
3 before 2007, was identified via hand review of
4 references from included citations.

5 So what are the benefit ratios for
6 different levels of frequencies of seafood
7 consumption? The proposed conclusion is Grade
8 2, simply because there is still a lot of
9 uncertainty about the size of the benefit-risk
10 ratio.

11 However, we feel comfortable
12 stating that health benefits derived from the
13 consumption of recommended levels of a variety
14 of seafood in the U.S. outweighed the risks
15 associated with methyl mercury exposure even
16 among pregnant and lactating women and young
17 children.

18 The implications are that seafood
19 is a healthy food choice that can be safely
20 promoted provided that the types and sources
21 of seafood to be avoided are clearly
22 communicated to consumers.

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1 The review of the evidence
2 identified three quantitative risk-benefit
3 assessments, one systematic review and one IOM
4 report which essentially was also conducted as
5 a systematic peer review.

6 Of these five studies, three are
7 very relevant to the U.S. One targets the
8 French population and one the Belgian
9 population. All took into account the risks
10 that you've seen there, and I'm not going to
11 read them because I will take you to a table
12 in a moment where you will see the specific
13 risks taken into account and benefits taken
14 into account by each of the studies. They
15 were using the term "seafood," but just based
16 on food consumption patterns, the analysis
17 really emphasized the modeling of fish,
18 consumption over other types of seafood.

19 So in terms of the three
20 quantitative analyses, the one by Ginsberg and
21 Toal, is, I think, a very relevant and
22 interesting one because what they did was to

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1 conduct the benefit risk analysis based on 16
2 seafood species. I believe they were seafood
3 because lobster was included -- 16 seafood
4 species commonly consumed in the State of
5 Connecticut, and obviously they concluded --
6 not all of them were commonly consumed, but
7 they also included purposely swordfish and
8 shark to make sure how it came out in the
9 analysis.

10 So those two, shark and swordfish
11 based on the benefit-risk ratios came under
12 the do not eat category avoidance consistent
13 with the previous report.

14 however, of the remaining species,
15 the great majority when it came to the
16 cardiovascular disease benefit-risk
17 assessment, there was no reason to advise
18 consumers not to consume them frequently. They
19 could consume them safely on a daily basis, a
20 portion of six ounces per day according to
21 their analysis, and when it came to
22 neurological development, they concluded that

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1 individuals could consume daily seven out of
2 the 16 species if that was their preference.

3 They called these recommendations
4 tentative because they did not take into
5 account persistent organic pollutants and
6 other possible contaminants in fish.

7 But what this study does, it does
8 call into question having a single generic two
9 meals per week recommendation for seafood when
10 there are different types of seafood, a lot of
11 seafood that perhaps could be consumed more
12 frequently.

13 Geuvel and colleagues conducted a
14 risk-benefit analysis using the quality
15 adjusted life year gains approach, and what
16 they did was to model in France using the
17 CALYPSO study data that was done in four
18 coastal communities, and they modeled what
19 would happen in terms of increase risk and
20 benefit if individuals moved from consuming in
21 the lower quintile moved to the upper quintile
22 in terms of their seafood consumption.

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1 And they found strong QALY gains
2 associated with the cardiovascular disease
3 outcome and modest QALY gains with a
4 neurological development outcome, and
5 obviously the neurological development related
6 to Omega-3 fatty acids contained in seafood.

7 I do want to mention that even
8 those consumers in the lowest quintile in
9 France, they consumed much more fish than the
10 U.S. population. So the background seafood
11 consumption is very high in the French
12 population.

13 And Sioen and colleagues, what
14 they did was to look at intake of seafood and
15 see if the intakes of Omega-3 fatty acids in
16 relationship to the intakes of perhaps methyl
17 mercury and persistent organic pollutants and
18 see how those look.

19 What they concluded was that three
20 fish meals per week would meet the Omega-3
21 fatty acid recommendation for the Belgian
22 population, keeping methyl mercury and POPs

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1 intake within safe levels. Their advice was
2 for those fish meals that it was appropriate
3 as long as it was half of them oily, which are
4 high in Omega-3, and half of them lean to
5 lower the risk of exposure to POPs.

6 So the highlight from that study
7 is that a variety of seafood should be
8 recommended with different fat content.

9 And in terms of the systematic
10 reviews, the IOM report emphasized heavily
11 three large prospective cohort studies from
12 the Seychelles Islands, the Faroe Islands and
13 New Zealand, and the systematic review,
14 qualitative in nature, ended up endorsing the
15 2004 advisory for the same target groups, but
16 it extended the recommendation, which became
17 more liberal, to groups beyond pregnant and
18 lactating women and young children because
19 they could benefit from the Omega-3 fatty acid
20 intake in terms of, you know, cardiovascular
21 disease without being very concerned about
22 possible harm that related to methyl mercury.

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1 The relationship between methyl mercury and
2 cardiovascular disease is still in question at
3 the levels of consumption that people are
4 usually exposed to.

5 And the systematic review by
6 Mozaffarian and Rimm also looked at all of the
7 possible documented benefits and risks for
8 Omega-3 fatty acids, methyl mercury, and POPs,
9 specifically PCBs and dioxin-like compounds,
10 and what is very interesting from this
11 analysis is that when they look at the
12 benefit-risk ratio in terms of coronary heart
13 disease, mortality prevented as a result of
14 increased Omega-3 fatty acids in relationship
15 to potential increased cancer mortality
16 associated with additional exposure or
17 increased exposure to POPs, they concluded
18 that the benefit-risk ratio for farmed salmon
19 was 100 to 300 across different age groups,
20 and for wild salmon it was even bigger, 300 to
21 more than 1,000, and the reason it's bigger
22 for wild salmon than from farmed salmon is

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1 that wild salmon tends to have lower levels of
2 POPs.

3 But any way you look at it, you
4 know, the benefit-risk ratio is substantially,
5 substantially in favor of recommending,
6 advising the public that based on the current
7 data that we have consuming a variety of
8 cooked seafood in the U.S. is beneficial.

9 MEMBER CLEMENS: Comments? Tom.

10 MEMBER PEARSON: The fatty acid
11 subcommittee obviously has had an interest on
12 this from the Omega-3, and we're not going to
13 be reporting those today, but just to share,
14 we've had two Webinars on this, one from
15 Professor Tom Brenna from Cornell and the
16 other from Dr. Joseph Hibbeln from NIH.

17 I'm fascinated with these benefit-
18 to-risk ratios because it seems that there's
19 even more new data in the last year or two
20 that would since jack that up even higher. The
21 irony of this whole thing, of course, is that
22 the very group of individuals who are most

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1 sensitive to the methyl mercury, and that is
2 fetuses and early childhood, and obviously
3 implying pregnant women or women thinking
4 about getting pregnant, is obviously the same
5 where the DHA is the most impactful.

6 And one wonders if, in fact, with
7 this confusion, where that center of confusion
8 is as well. So we have a lot of work to do
9 about this, but I think certainly it seems
10 that the science is coming in extremely
11 strongly for perhaps even stronger and larger
12 recommendations for the DHA in this group than
13 before.

14 MEMBER CLEMENS: Rog here.

15 I appreciate your comments there,
16 Tom. In the next meeting we will discuss some
17 of the offsetting issues that might be
18 associated with methyl mercury in a positive
19 way. So I appreciate your comments very much.

20 Also, to pick up where Rafael
21 mentioned about in-home cooking and that of
22 Mim's, it's clear that we all are aware of the

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1 most recent E. coli issue affecting the beef
2 production. We also need to be aware that
3 these issues affect home processing or home
4 cooking. If we're going to undercook -- and I
5 think Rafael mentioned this -- if we undercook
6 the beef that we get wherever we get it,
7 either a cow from our back yard or from the
8 local box market, we need to cook it properly
9 and, to Rafael's excellent comment, by using
10 proper temperatures and cooking times.

11 We certainly know that, in fact,
12 with undercooked beef, it can lead to serious
13 illnesses in the home and children have died
14 as a result of undercooking beef. So we have
15 to be cautious about it and be more attentive
16 to the issues that affect us at home.

17 Any other comments?

18 CHAIRPERSON VAN HORN: What is the
19 evidence from places in our country where
20 seafood consumption is highest? One would
21 expect that, you know, if there really were
22 major problems, that we would see pockets of

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1 methyl mercury toxicity that occur there
2 because of these greater increases. Are we
3 going to hear any?

4 I mean, are there data to that
5 topic? Eric, you probably know.

6 MEMBER RIMM: This is Eric Rimm.

7 I think it's obviously a
8 challenging topic, and some of the initial
9 documentations of the dangers of methyl
10 mercury were in really highly toxic areas
11 where there is contamination.

12 And so it would be hard to capture
13 to the extent where there would be a pocket of
14 methyl mercury excessive consumption because
15 some of the neurologic effects are quite
16 subtle and sometimes take years and years and
17 years to develop. So some of the evidence
18 that's coming out now looking in the U.S.
19 looking at the impact of mercury on the fetus
20 is really looking at subtle changes in infants
21 and in four year olds and in six year old that
22 may be slight differences in IQ levels.

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1 So it would be kind of hard to
2 capture that as a pocket. So I don't think we
3 necessarily have huge contamination issues in
4 the U.S. It's just sort of subtle differences
5 between the benefits of Omega-3s and the
6 detriments of mercury.

7 MEMBER PEARSON: But the more
8 extreme experiments have also been done, and
9 those are in the Seychelles Islands and the
10 Faroes with really extraordinary fish
11 consumptions. Islands tend to eat a lot of
12 fish since they're surrounded by it, and that
13 was very long term. Those kids, I think, were
14 followed up into their early teens with almost
15 instant -- and there was also looking at
16 dental amalgams and other sources of mercury.

17 Since it was a Rochester group
18 that was doing part of it, we get seminars
19 quite frequently. As far as I could tell, the
20 more fish you ate, the smarter you were.

21 MEMBER CLEMENS: I appreciate you
22 bringing that. This is Rog. I appreciate you

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1 bringing that up. Obviously there are smart
2 people in New York. We will actually address
3 that study extensively in the next go-round.

4 Also, if we look at some of the
5 next steps we're examining as indicated on the
6 slide, constant personal hygiene is critical,
7 washing of hands. Sing "Happy Birthday" to
8 yourself when you wash your hands.

9 We also understand that the food
10 code will soon be updated for 2009, I
11 recollect, and Rafael and I are looking at
12 this very seriously, how that food code as
13 applied to the commercial environment can be
14 applied to our home. The various practices on
15 a large scale can, in fact, be applied in our
16 home operations.

17 So clearly, cleaning surfaces that
18 now have color coded surfaces in different
19 ways to actually improve sanitation
20 capabilities in the home; we will be
21 addressing some of those technologies in our
22 next meeting.

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1 Obviously as a big issue to
2 opportunity to increase a variety of foods,
3 some of those foods are at risk whether
4 they're locally grown or commercially
5 available. So clearly we need to be sure that
6 we handle them the most appropriately, and
7 those appropriations indicated here, fruits
8 and vegetables, and so forth as indicated
9 here. Clean and separate are critical in the
10 home.

11 Obviously comments by Rafael and
12 the comments by those who were listening to
13 this conference, undercooking and managing
14 foods appropriately in the home is really
15 critical to maintain the health in the home as
16 well as to underscore the importance of
17 minimizing any foodborne outbreaks, including
18 picnics and so forth that we have at
19 gatherings.

20 So we look at new techniques, and
21 techniques that affect packaging, the
22 techniques that improve food storage. Those

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1 kinds of issues will certainly be addressed at
2 the next meeting, and the clicker is --
3 Rafael, do you want to comment here?

4 MEMBER PEREZ-ESCAMILLA: Yes. The
5 idea was to see if we could identify
6 additional benefit risk assessments based on
7 seafood species. We think that for consumers,
8 consumers tend to prefer certain species, and
9 the most useful guidance, I think, at the end
10 of the day is to provide them with access as
11 to entering their preferences and hopefully
12 databases will have information to compute the
13 benefit-risk for them.

14 Domingo and colleagues have
15 exactly done that in Spain and here in the
16 U.S. we have the cooperative extension system
17 with Dr. Santerre leading a very important
18 effort at giving access to consumers through
19 the Web for determining their risk, benefit-
20 risk of the consumption.

21 MEMBER CLEMENS: The consumers are
22 clearly asking for something more definitive,

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1 and our goal is to provide more definitive
2 guidance in the consumption of seafood type
3 products.

4 Cheryl.

5 MEMBER ACHTERBERG: It occurs to
6 me that while I guess consumers are cooking
7 once a week, which is surprising to me, they
8 are watching these chef cooking shows more
9 often than that, and that might be the best
10 vehicle to communicate some of this
11 information.

12 MEMBER CLEMENS: I appreciate that
13 remark. One of my daughters is a chef. So
14 actually a lot of the practice that you see on
15 those cooking shows are inappropriate when it
16 comes to food safety. this is a no-brainer.
17 So they are educating the public and will do
18 it "don't do what I do, but do what I say."

19 So clearly, actually I personally
20 have a movement through the Food Network to
21 try to educate some of the chefs and bring
22 that to light, and we're hoping that through

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1 the process we can actually get a food safety
2 message out through that program. Excellent
3 comment.

4 Others?

5 MEMBER APPEL: Yeah, this is
6 Larry.

7 I always like to think about
8 implementation even though that violates the
9 rules, but it seems to me that food safety is
10 one of those areas where we don't really have
11 a great model for transmitting information. I
12 think it's sort of haphazard through
13 newspapers. Is there any thought to -- I
14 mean, you know, if you do get information
15 about nutrition or food safety maybe in
16 schools, if not at a point where you're
17 actually doing a lot of active food
18 preparation -- so has there been any thought
19 about how to do this better?

20 Because I think that's where
21 probably the money is.

22 MEMBER PEREZ-ESCAMILLA: Yes.

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1 Well, I think, you know, that the FightBac!®
2 Campaign is a very nice example of a
3 partnership that involves government and
4 industry and so on that, you know, has
5 increased the level of awareness, level of
6 knowledge about food safety in the country.
7 They use many different venues to transmit
8 this information to the public.

9 But a very, very big obstacle is
10 the issue of risk perception. If people are
11 not convinced that this is a risk for them in
12 their homes, how likely it is that they're
13 going to follow the advice.

14 So what Mim was requesting, I
15 think, is very crucial. It's very key. Can
16 we quantify better the risk of foodborne
17 illness at home as a result of us not handling
18 the food properly in our home, in our home
19 kitchens?

20 MEMBER APPEL: Let me just follow
21 up on that. Larry Appel again.

22 I'm just wondering though. I

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1 guess you didn't do research recommendations,
2 but one research recommendation would be to
3 develop and test innovative strategies because
4 I think that even that probably will still be
5 tough, you know, and you know, whether there
6 are ways that you can do it at point of
7 purchase or at end of purchase or, you know,
8 something that -- because I think that this is
9 an area where we just don't have the right
10 model in place.

11 MEMBER PEREZ-ESCAMILLA: And,
12 again, it goes back to children and teaching
13 kids in schools the principles behind cross-
14 contamination. I think it would go a long way
15 at our efforts to make it easier to explain to
16 the public why it is important to do what we
17 are advising them to do.

18 CHAIRPERSON VAN HORN: One thing
19 that wasn't mentioned that I think we talked
20 about last time, but I'd love an update on
21 this or just finding out where it is at this
22 point, and that has to do with fish farming

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1 and aquaculture, recognizing as we were told
2 somewhere along the line that, you know, the
3 importance of fish farming will just continue
4 to rise as people are recommended to eat more
5 fish, and that there were some problems
6 earlier. I am aware specifically at least
7 over the last five years or so that food being
8 fed to fish being farmed -- say that ten times
9 fast -- it was actually contaminated.

10 And so the idea of, you know,
11 trying to hone in on that source because I
12 know the public is totally confused about wild
13 caught fish, farmed, you know. You have a
14 benefit by choosing one over the other, and I
15 think nutritionists are likewise not sure what
16 to tell people.

17 MEMBER CLEMENS: Thank you for
18 that comment, Linda.

19 Indeed, the consumer is much
20 confused over that very issue. I appreciate
21 that. We do know after that one big incident
22 that we're all aware of. We know that the

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1 industry has actually cleaned up the feed
2 greatly, and there's actually greater
3 attention to that.

4 In addition, too, the pending
5 bills on the Hill will mandate better clean
6 feed that we give to those fishes that are
7 being farmed.

8 And relative to food safety, as
9 you know, there are a lot of bills on the Hill
10 being discussed as we speak, and there's also
11 a very important good safety conference, and,
12 Rafael, I think you're speaking at that one,
13 in March in Atlanta.

14 (Laughter.)

15 MEMBER CLEMENS: Well, one of us
16 is speaking in Atlanta.

17 MEMBER PEREZ-ESCAMILLA: That's
18 why I came to this meeting, to find this out.

19 (Laughter.)

20 MEMBER CLEMENS: The point is it's
21 a public conference that will be done on food
22 safety in Atlanta done by the CDC. Of course,

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1 it will be addressing this very important
2 topic. So stay tuned and practice better
3 health.

4 We'll be discussing better
5 technologies in the future. Rafael did an
6 excellent job commenting about the cleanliness
7 or lack thereof of refrigerators. Have you
8 checked your microwave ovens lately?

9 (Laughter.)

10 MEMBER NICKOLS-RICHARDSON: This
11 is Shelly.

12 I just want to comment that there
13 is a system in place, and it's called the
14 Cooperative Extension Service, and as cuts are
15 made to that program, part of the impact of
16 what happens has been the consumers, the
17 public, are not as well educated about topics
18 like food safety, about how to farm well, and
19 all of those issues that surround our food
20 supply, as well as how we handle, process and
21 then how that relates to health and wellness.

22 So there is that system, and I

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1 think as much as USDA as a whole can tap into
2 its different parts, then we'll do better for
3 the public.

4 MEMBER PEREZ-ESCAMILLA: Wonderful
5 comment, Shelly, and I do want to mention
6 that, you know, low income consumers, women of
7 reproductive age, major source of food safety
8 information for them is WIC program, and in
9 fact, some researchers are attributing
10 improved food safety behaviors as a result of
11 perhaps the education that is done oftentimes
12 in cooperation with the Cooperative Extension
13 System.

14 So that's really important, and
15 very briefly, I wanted to mention to what was
16 your question, Linda, that as we presented to
17 the science review subcommittee what we will
18 try to do is to understand better how
19 government and industry -- what are they doing
20 to try to monitor the levels of diverse
21 contaminants in the food supply because
22 consumers think that they're taking care of

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1 it, and I think we may be surprised and they
2 may be surprised that there is a lot in their
3 hands to do to minimize the risk.

4 MEMBER CLEMENS: And in closing,
5 thank you for the comment about the extended
6 service and really wonderful education
7 opportunities through that to happen.

8 As the country calls for more
9 locally grown products, whatever that means,
10 it's clear that food safety is paramount at
11 locally grown products, and we have to ask
12 ourselves who's monitoring the henhouse when
13 locally grown products are actually being
14 distributed throughout the community.

15 While this movement is gaining
16 momentum, I think from a food safety
17 perspective we need to address some of these
18 issues.

19 CHAIRPERSON VAN HORN: Perhaps one
20 model of this, I mean, I'm reminded that
21 Thanksgiving is approaching, and I think one
22 of the most successful models suggesting what

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1 you just were mentioning, Rafael, between
2 industry partnering with government relates to
3 the turkey hotlines that are out there that
4 are extremely well tapped into during this
5 time of year as people have a million
6 questions about how to thaw turkey safely and
7 all of the things that go along with that.

8 That model, you know, is something
9 that perhaps could be given additional thought
10 for other venues, including this one, you
11 know, related to ways to get the word out in a
12 user friendly manner.

13 Mim, you had another question?

14 MEMBER NELSON: Yes. So two
15 questions. One of which is back to the
16 schools. I mean, not necessarily bringing
17 back home ec, which is gone pretty much now. I
18 feel like we've lost two generations of
19 children and adults that don't know how to
20 cook, and I think that there may be a way to
21 think back into the health curriculum of
22 schools to get cooking, safe cooking, you

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1 know. Also, a lot of people go into that
2 profession. I mean, there's a jobs piece to
3 that.

4 I'd like to try to resurrect
5 cooking, safe cooking skills, et cetera, but
6 that's just a comment.

7 But is there any reason -- I don't
8 know this data. So I'm asking, but it's
9 following up to what Linda said -- is there
10 any reason that there should be from a health
11 perspective benefit between farmed fish versus
12 while caught?

13 And that's one that nobody has
14 done, and is there any reason why we because
15 there's more evidence, or not, that we should
16 be having any differential recommendation in
17 terms of the health benefits?

18 MEMBER RIMM: This is Eric Rimm.

19 I mean, that's the question that I
20 think Rafael nicely put, is that when you're
21 looking at the benefit versus risk, there's
22 somewhere between 300 to 1,000 times more

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1 benefit than there is risk for eating fish,
2 regardless of where it comes from. So I think
3 the Omega-3 benefit is so much more than any
4 small contaminant that you would get in fish.

5 That doesn't mean it doesn't need
6 to be monitored. It doesn't mean it doesn't
7 need to be controlled over the feed, but the
8 fact of the matter is that we're measuring
9 things in parts per billion or parts per
10 trillion.

11 You know, if we measured all of
12 the food we eat, there's lots of contaminants
13 in the parts per billion and parts per
14 trillion. In fact, most of the contaminants
15 we get are not in fish. They're in dairy,
16 they're in beef, and they're in chicken than
17 they are in fish.

18 So I think that there obviously is
19 a bit of I don't know if it's a scare or it's
20 just publicized better that it's been in fish
21 because people have measured it, but the fact
22 of the matter is that that's not where we get

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1 most of our contaminants from.

2 MEMBER NELSON: No. I guess I was
3 actually looking at the flip side. Is there
4 any reason why we should be stating that it
5 would be better to eat wild caught fish than
6 farmed fish, not that there's no evidence?

7 MEMBER RIMM: Well, some of it is
8 price. Some of it is, you know, impact. Does
9 it impact the environment differently? If we
10 all ate fish ever day, obviously we couldn't
11 support that in this country. There's not
12 enough food to support the farm fishing
13 industry. So some of it is just an
14 environmental demand, that if we all ate too
15 much fish all the time or if it was all farmed
16 it would be an issue.

17 But I think other than that, you
18 know, I don't think there is necessarily a
19 strong push to say we all should be eating
20 wild fish as opposed to farmed.

21 MEMBER PEREZ-ESCAMILLA: A
22 colleague of mine at a conference, the way he

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1 framed these was in some countries chicken
2 tastes like fish, and in other countries fish
3 tastes like chicken because it depends a lot
4 on how they are fed.

5 MEMBER NELSON: They're fed the
6 same thing.

7 MEMBER PEREZ-ESCAMILLA: So again
8 --

9 MEMBER NELSON: So I guess that's
10 why I guess I'm asking. Because the wild
11 caught is actually eating different food.

12 MEMBER PEREZ-ESCAMILLA: Right.

13 MEMBER NELSON: You know, they're
14 eating more naturally.

15 MEMBER PEREZ-ESCAMILLA: Consumers
16 want to know how the farm fish was fed. That's
17 kind of what we're trying to get at, yeah.

18 MEMBER CLEMENS: In closing, we
19 will be addressing some of the new
20 technologies that are emerging to provide a
21 better environment so that we can have safer
22 food. We'll be addressing these in the next

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1 go-around, and also in the next go-around,
2 we'll be discussing these important topics:
3 food allergy, which was not addressed the last
4 go-round. We certainly see that it was hit
5 hard in 2006, and we want to address some of
6 those issues.

7 Now, a lot of people are becoming
8 much more sensitive to more than just the
9 basics. We'll be discussing that.

10 Clearly organic food is on a lot
11 of people's hit list. So let's talk a little
12 bit about organic.

13 We'll also be discussing other
14 things, things other than microbial issues. A
15 lot of people think food contamination, food
16 safety is focused on methyl mercury or
17 microbes. It's bigger than that. Actually
18 every food contains something that nature puts
19 there to protect the food, and so we have to
20 be careful how we put things together and what
21 we call those things, contaminants or
22 naturally occurring components.

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1 Also it's important to note that
2 the FDA came out with a position not too long
3 ago that farmed fish may have higher levels of
4 N3 fatty acids. Again, to pick up on what
5 Linda commented, it really, again, depends on
6 some of the feeds that are provided some of
7 those fish and the kinds of fish, obviously.

8 Other comments?

9 So now you're ready to have a safe
10 lunch.

11 (Laughter.)

12 CHAIRPERSON VAN HORN: That's
13 right.

14 Roger, Rafael, thank you very
15 much. That was excellent, and I want to thank
16 all the committee members for a lively and
17 very productive discussion today so far.

18 Now it's time for a lunch break.
19 Indeed, wash your hands and move around, and
20 we'll see you back here at one o'clock Eastern
21 time.

22 Thank you.

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1 (Whereupon, at 12:04 p.m., the
2 meeting was recessed for lunch, to reconvene
3 at 1:00 p.m., the same day.)
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1 from Patricia Guenther, Molly McGrane, and
2 Thomas Fungwe. So just thanks to all of them
3 as we've gone through this literature.

4 I just want to talk a little bit
5 about some terminologies in your slides.
6 You'll see some of these. So if I go rapidly
7 what an iTFA is, you'll know that it's an
8 industrial *trans* fatty acid, and we may not be
9 as jargonous as the geneticists, but we're
10 getting close. So these are some of the terms
11 that we'll be using today.

12 I'd like to begin by putting this
13 into context, and this is a committee that I
14 sat on for the American College of
15 Cardiology, looking at the number of patients
16 with heart disease over the next half century.
17 We're currently at about 12.4 million
18 Americans have heart disease, and by 2050 that
19 number will be about 25 million.

20 And what this is a consequence of
21 is several things. Number one, the good news
22 is that we're doing a great job in patients

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1 who develop heart disease, keeping them alive.
2 Our case fatality rates have fallen by about
3 75 percent. That's the good news.

4 The bad news is that we really
5 haven't affected incidence, and as I'll
6 mention, is it the new cases are still
7 appearing? And the consequences of this graph
8 is tremendous levels of disability, health
9 care cost, and it's all preventable.

10 So the epidemiologic background of
11 all this is that while mortality continues to
12 fall, the incidence of coronary heart disease
13 does not appear to have declined since about
14 1990 so that the new cases are still filling
15 the reservoir.

16 Correlating with that is serum
17 cholesterol levels correlate with coronary
18 heart disease rates on a worldwide basis, and
19 you've all seen the ecologic graphs with
20 coronary heart disease mortality rates and
21 serum cholesterol levels.

22 Serum cholesterol levels in the

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1 United States appear to have been stable since
2 1990. This is actually despite the widespread
3 use of effective cholesterol lowering drugs,
4 which is now certainly an industry in the
5 multiple billions of dollars. So if
6 everything would have remained the same, one
7 might have expected to have a decline in serum
8 cholesterol, and that may, in fact, be
9 happening in the least-last few years, but the
10 question is what are we doing about the diet.

11 So these are just some data from
12 the Minnesota heart survey showing that from
13 1980 through about 2000 this early decline in
14 the 1980s and then the planing off of that
15 leaving us with average total cholesterol
16 levels of 200 to 205 milligrams per deciliter,
17 and you can see there hasn't been any change
18 in the HDL either.

19 So this is really the challenge,
20 is where we're going to go from here,
21 particularly in a public health way, not in a
22 pharmacologic way?

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1 Further epidemiologic background
2 is that the relationship between saturated fat
3 and cholesterol is well established, and this
4 has been cited in previous dietary guidelines
5 as well as numerous other guidelines,
6 professional science societies, et cetera, and
7 there is little evidence that dietary
8 saturated fat and cholesterol intakes have
9 changed since the 1990s.

10 And here what we can see is that,
11 again, Minnesota, this is the NHANES data,
12 looking at 2000 versus 1994. You can see that
13 this is total cholesterol in millimoles per
14 deciliter, on the left there being around 1990
15 NHANES III data and then NHANES in 2000, and
16 you can see for men there really hasn't been
17 any change at all, perhaps a slight decrease
18 in women, despite a tripling of cholesterol
19 lowering drug use now in upwards of ten
20 percent of the American population.

21 So one of our first PICO questions
22 really had to do with what is the evidence of

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1 implementing dietary guidelines for fats, and
2 this is one of the questions that we had, is
3 how did intakes of fat and cholesterol by
4 Americans change between 1977 and 2005,
5 according to national dietary surveys, and we
6 had shown you some of these data previously,
7 but we now -- the staff has been able to
8 provide us with quite more data and organized,
9 I think, well.

10 And on this chart what we see is
11 intake of fats as percent of energy for all
12 persons, and what we can see here is that we
13 have data points from the late 1970s and
14 around 1990, but there is, I think, ample
15 reason for concern for methodologic
16 differences in these early nutritional
17 surveys, although I think they're useful for
18 putting this into context.

19 But certainly we also have, using
20 the same methodologies, NHANES data from --
21 kind of chasing each other around there --
22 NHANES data from 2001 now to 2006, especially

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1 three data points. And I think the message is
2 that I think there's pretty solid evidence to
3 suggest that total fat consumption hasn't
4 really changed at all, right around 33 to 34
5 percent, and the saturated fat has really been
6 unchanged since, say, the mid-1990s at 11 to
7 11 and a half percent.

8 Similarly, polyunsaturated fats
9 and monosaturated fats as percent of calories
10 has been quite steady, and you can see, again,
11 probably due to some methodologic differences
12 an increase in total energy, suggesting there
13 may, in fact, be an increase in grams per day
14 of these fats.

15 So I think the point is that given
16 our epidemic of coronary disease with the
17 incidence being stable and certainly the
18 ecologic evidence we have of the importance of
19 the diet and establishing population-wide
20 cholesterol levels, the question is what do we
21 do about these levels of saturated fat that
22 have been basically stuck at 11 and a half

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1 percent.

2 We also have now data for men
3 versus women, and I think the point here is
4 that it's pretty much the same, and what we
5 can see is saturated fat, about 11 percent in
6 men, polyunsaturated and monounsaturated and
7 again very little change between the mid-1990s
8 and 2006.

9 Similarly for women, you see the
10 same with the same amount of saturated fat as
11 percent of calories, possibly a little bit of
12 increase in polyunsaturated fats, but still
13 again very little change over the 1995-2000
14 and up to the 2005 guideline periods.

15 So one of the next questions that
16 we addressed was what is influence of dietary
17 fat on cardiovascular disease and other health
18 outcomes, and for this there obviously had
19 been prior guidelines, including the 2005,
20 which has reviewed this, and what our
21 intention here was to update these databases
22 out to saturated fat and cholesterol.

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1 And as we'll show you, we're going
2 to be presenting in February monounsaturated
3 and polyunsaturated fat in this similar
4 context.

5 And here we see the inclusion
6 criteria for our searches. We initially had
7 done 2004 to current, 2009, but in certain
8 circumstances we would go back to 1999
9 depending on the specific topic. We looked at
10 both healthy subjects and those at elevated
11 chronic disease risk, as well as some disease
12 subgroups as we'll show you, particularly
13 people with Type 2 diabetes or at risk for
14 them.

15 Something else that we had done
16 similar to some of the other groups, and that
17 is stayed away from cross-sectional studies
18 and limited our looks at randomized trials or
19 prospective cohort analyses and meta-analyses.

20 For the feeding studies, given the
21 asymptoting of particularly lipid levels, we
22 had limited the search to those with a feeding

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1 period of greater than four weeks, in diabetic
2 outcomes to greater than six weeks.

3 So just to remind you is that
4 there really don't appear to be large
5 differences in saturated fat intake in men
6 versus women. So the real reference point
7 here would be an 11 to 11 and a half percent
8 saturated fat as percent of calories as to
9 where we are currently.

10 So the first question is what is
11 the effect of saturated fatty acid intake on
12 the risk of cardiovascular disease, which is a
13 previously reviewed question, but added to
14 this was the Type 2 diabetes as an endpoint,
15 and then intermediate markers such as at the
16 lipoprotein levels, measures of insulin
17 resistance and inflammation, the latter of
18 which we really hadn't seen many papers for.
19 So this is largely the diabetic and lipid
20 intermediate markers.

21 The review included 12 studies
22 since 2004, ten randomized trials, one non-

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1 randomized clinical trial, and one analysis of
2 11 pooled cohorts.

3 The evidence review showed that
4 saturated fatty acid replacement was five to
5 seven percent of energy with MUFAs or PUFAs,
6 where largely the comparisons we're talking
7 about. This is important because this is not
8 a replacement with carbohydrates, which is the
9 second point. So most of the data relatively
10 have a set amount of total fat, and the
11 comparisons and the tradeoffs are within the
12 total fat amount.

13 These showed significant
14 reductions in total LDL cholesterol in about
15 nine trials, and in one trial improved levels
16 of less atherogenic LDL particle size.

17 When it came to saturated fat
18 replacement with carbohydrates, it was reduced
19 total LDL cholesterol, but this was a bit of a
20 less favorable situation with decreased HDL
21 and increased triglycerides in that data set.

22 And the PUFA analysis of 11 cohort

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1 studies showed replacing saturated fats
2 modeled to five percent of energy, reduced CHD
3 events in middle aged and older adults.

4 Now, in terms of the second step
5 of this was saturated fatty acids in Type 2
6 diabetes. This, again, was not included in
7 the 2005 guidelines, and this had ten studies
8 of seven randomized trials, one prospective
9 cohort study and two systematic reviews.

10 The evidence here showed
11 replacement of saturated fat with mono and
12 polyunsaturated fatty acids was, again, mixed.
13 Of the 12 trials, insulin sensitivity was
14 improved in three of the trials and was not
15 changed in nine of the trials.

16 There were four trials which
17 showed a reduction of saturated fatty acids
18 leading to increased insulin sensitivity
19 without a comparison group with the MUFAs and
20 the PUFAs, and there was the reduced
21 saturated fat intake decreasing risk of Type 2
22 diabetes in three studies. The two Lindstrom

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1 studies were two different studies, just a
2 redundancy there, as the basis for our
3 conclusions, which with Grade 1 evidence was
4 that dietary saturated fat is positively
5 associated with intermediary markers and
6 endpoint health outcomes for two chronic
7 diseases now increased serum total and LDL
8 cholesterol with an increased risk of
9 cardiovascular disease and increased markers
10 of insulin resistance and increased risk of
11 Type 2 diabetes.

12 Conversely, decreased saturated
13 fatty acids intake improves measures of both
14 cardiovascular disease and Type 2 diabetes
15 risk.

16 Specifically, and given the
17 granularity leading to a Grade 1
18 recommendation of the evidence, the evidence
19 shows that a five percent energy decrease in
20 saturated fatty acids when replaced by MUFAs
21 or PUFAs, decreases risk of cardiovascular
22 disease and Type 2 diabetes in healthy adults

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1 and improved insulin responsiveness and
2 insulin resistance in Type 2 diabetes
3 patients. So those are the conclusions from
4 that evidence and that question.

5 The implications of this is,
6 again, with the other working groups relative
7 to energy balance, et cetera. We're working
8 with really no change in total fat consumption
9 here, with replacement of saturated fats with
10 mono and polyunsaturated fatty acids rather
11 than with carbohydrates as the basis for our
12 discussions.

13 Another nuance is the addition of
14 a second chronic disease, diabetes, as a
15 possible driver for saturated fatty acid
16 reductions, and then the suggestion that
17 replacement of five percent of saturated fatty
18 acid calories with MUFAs and PUFAs would
19 correlate essentially with the current, say,
20 11, 11 and a half percent of saturated fat
21 calories from energy, so saturated fat level
22 of less than seven percent advantage, the

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1 implications for that evidence review.

2 In terms of cholesterol intake,
3 the question is what is the effect of
4 cholesterol intake on increased risk of
5 cardiovascular disease, including these
6 intermediate outcomes, such as lipid
7 hypoprotein levels and markers of
8 inflammation. Again, not a lot of literature
9 on the markers on inflammation.

10 These are the current and last 30
11 years or so look at cholesterol intake in
12 milligrams per day, and I think what you can
13 see is that in men there are currently above
14 the 300 milligrams per day, and that this
15 level has been very stable certainly within
16 this decade and probably before that as well.

17 And for women, you can see that
18 they're considerably below the recommended
19 level, and again, this has to do with this
20 issue of how many total calories are being
21 consumed, which obviously differ between men
22 and women.

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1 So this is the discussion we had
2 earlier during Larry's presentation. How
3 should consumption of cholesterol be expressed
4 or targeted or whatever verb you'd like to use
5 up there? Milligrams per day, which is the
6 status quo; milligrams per day by level of
7 caloric intake, which I think is borrowing
8 from Larry's stratification of different
9 levels of diet; or just milligrams were 1,000
10 calories, and I think this is an issue. We've
11 heard now from Fiber and others, and I think
12 this is something we should really come to
13 some consensus about. But you can see from
14 the men and the women are a bit different
15 there.

16 I have a note here saying I've
17 added a couple of slides at the end here. So
18 you may not have all of the slides, but they
19 will be available for you later.

20 In terms of cholesterol and
21 cardiovascular disease, the review of the
22 evidence, there were 16 studies reviewed since

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1 1999, eight randomized trials, five
2 prospective cohort studies, one meta-analysis,
3 and two reviews. So the cholesterol study
4 continues to be told.

5 The evidence review for randomized
6 control trials is that we now have evidence,
7 data that in previous years about 30 to 40
8 percent of dietary cholesterol was in the form
9 of one food, that is, eggs. This apparently
10 had reduced via less consumption of eggs and
11 possibly less cholesterol in the eggs, to
12 about 25 percent of cholesterol comes from
13 that source. It still is the largest source,
14 and many of the randomized controlled trials
15 were -- industry supported over half of them,
16 in fact -- looking at egg versus egg
17 substitutes or eggs versus no eggs. And at
18 least two studies showed an elevation of LDL
19 and HDL in hyper responders, but no change in
20 hypo responders, leaving open this issue of
21 genetic predispositions, and six of those
22 studies were negative.

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1 There also was a meta-analysis of
2 17 studies of high cholesterol intake, and its
3 --

4 MEMBER PI-SUNYER: What do you
5 mean by negative?

6 MEMBER PEARSON: There is no
7 change, yeah, no change in the entire group,
8 yeah.

9 And meta-analysis of 17 studies
10 with high intake on total LDL over HDL ratio
11 showed no changes, and this is consistent with
12 the IOM report previously with 49 randomized
13 trials.

14 Now, quite different in terms of
15 funding sources, there were a number of large
16 and particularly federally funded studies
17 prospective studies, which again looked at
18 particularly egg consumption. Egg consumption
19 of up to seven eggs per week was not
20 associated with increased mortality, and you
21 can see the number of large prospective
22 studies there.

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1 Egg consumption of greater than
2 seven eggs per week was a little bit less
3 consistently with one study showing an
4 association and one study not.

5 But in three of the studies they
6 did look at this Type 2 diabetes subgroup and
7 three of those studies was able to show a
8 consumption was related to coronary heart
9 disease in patients with Type 2 diabetes.

10 And with the exception of the Type
11 2 diabetes finding, this was consistent with
12 the IOM report.

13 So the proposed conclusion for
14 cholesterol and cardiovascular disease is that
15 there's a lack of consistency in epidemiologic
16 studies relating dietary cholesterol to
17 clinical cardiovascular disease endpoints.
18 However, many studies on dietary cholesterol
19 use eggs as a dietary source. Independent of
20 other dietary factors, evidence suggests that
21 there is no association between consumption of
22 one egg per day and risk of CHD or stroke in

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1 health adults, although consumption of greater
2 than seven eggs per week may increase risk.

3 An apparently important and quite
4 consistent exception is that dietary
5 cholesterol has been associated with
6 cardiovascular disease risk in individuals
7 with Type 2 diabetes.

8 We addressed a couple of other
9 questions in the area of dietary fat,
10 components affecting serum lipids and
11 lipoproteins. Two of the other issues that we
12 addressed were stearic acid and natural versus
13 industrial *trans* fatty acids.

14 This is the intake in grams per
15 day of stearic acid across time. You can see
16 that if anything the stearic acid has been
17 increasing. Stearic acid, of course, is
18 labeled as a saturated fat. It's the C18:0
19 fatty acid, and what perhaps the nuance here
20 is is that actually there's quite a bit of it
21 in the diet, particularly in the form of red
22 meat, and this constitutes somewhere between

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1 -- the 2005 guideline listed it as about three
2 and a half percent of total calories on the
3 average in the diet, and more recent we've
4 provided you with some of the tables in the
5 handouts, and it looks like about two and a
6 half percent.

7 But the point is it has got a
8 sizable contribution to calories, particularly
9 if you're going to be thinking about changing
10 its inclusion as a cholesterol raising fat,
11 which is the current implication of including
12 it as a saturated fat along with other
13 saturated fatty acids.

14 So the real question then, the NEL
15 question, was what are the effects of dietary
16 stearic acid on LDL cholesterol, and the
17 review of recent studies looks at two
18 randomized controlled trials and one
19 systematic review. When stearic is
20 substituted for carbohydrates, there's no
21 effect on the LDL levels in two randomized
22 trials, and only one of those two trials found

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1 also a decrease with stearic acid substitution
2 to decrease HDL cholesterol.

3 And this meta-analysis by Mensink,
4 et al., found no significant diet induced
5 changes in LDL or HDL, but a small but
6 significant reduction in triglyceride levels
7 with stearic acid.

8 So the proposed conclusion with
9 Grade 2 level of evidence is that based on
10 randomized controlled trials, replacement of
11 energy from carbohydrates with stearic acid
12 has a neutral effect on LDL cholesterol.
13 Potential impact of stearic acid on
14 cardiovascular disease risk in general remains
15 unclear, but certainly it does not appear to
16 be like the other C12 through C16 saturated
17 fats that have a cholesterol raising effect.

18 The other question we had on *trans*
19 fatty acids was what effect does consuming
20 natural versus synthetic, that is, industrial
21 *trans* fatty acids have on serum lipids and
22 lipoproteins. So in this instance it's

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1 somewhat of a smaller question. Obviously
2 there's been the -- in the 2005 guidelines the
3 recommendation to lower *trans* fatty acids as
4 much as possible, and the question is are
5 there from these two sources any evidence that
6 one may be carrying the risk of the LDL
7 raising and the HDL lowering effect which has
8 been so well documented.

9 So just to put this in context,
10 the exposure of *trans* fatty acids is that the
11 RTFA, which is the ruminant that's a natural
12 *trans* fatty acids is really quite small in the
13 U.S. adult population, approximately 1.2
14 grams. You can see the difference for men and
15 women, and it's estimated to represent 0.5
16 percent of total daily energy intake. So a
17 relatively small amount.

18 So even if there is some
19 difference, the effect of this ruminant just
20 given the low exposure is probably going to be
21 minimum in terms of a public health effect.

22 Nonetheless, there were the four

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1 studies to review, three prospective cohort
2 studies and one case control study, and
3 basically with Grade 2 evidence the proposed
4 conclusion, it's well documented that
5 industrial *trans* fatty acids adversely affect
6 the LDL, HDL and non HDL cholesterol levels,
7 but evidence is limited that ruminant TFA
8 levels typically consumed have any effect on
9 cardiovascular disease or coronary disease
10 risk, and based on the results of these two,
11 small, well designed cross-over studies
12 listed below, high intakes or ruminant *trans*
13 fatty acid do not show consistent or different
14 effects than industrial *trans* fatty acids.

15 One study found that ruminants
16 *trans* fatty acids compared to industrial *trans*
17 fatty acids increased both LDL and HDL
18 cholesterol in women but not in men, but
19 certainly there wasn't any suggestion that
20 these ruminants, natural *trans* fatty acids
21 were certainly safer than the industrial ones,
22 which was the previous point.

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1 The three prospective cohort
2 studies and one case control study using
3 coronary heart disease endpoints show no
4 significant differences in association between
5 ruminants and industrial *trans* fatty acids and
6 basically corroborate the studies and the
7 effects on lipids and lipoproteins, and so the
8 proposed conclusion is that the total *trans*
9 fatty intake would be considered a target of
10 dietary change, and there really isn't any
11 reason to separate these into industrial
12 versus ruminant, and obviously the previous
13 recommendations had to reduce the consumption
14 of those as low as possible.

15 In terms of remaining research
16 topics, we will be presenting in similar
17 format the next time on what is the influence
18 of dietary fat on coronary disease and other
19 outcomes. You can see that this is the
20 monounsaturated fatty acids and, in general
21 polyunsaturated fatty acids is the other side
22 of the saturated fatty acid coin since most of

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1 our data are talking about the substitution of
2 MUFAs and PUFAs for the saturated fat. So
3 it's the other side of the evidence that we
4 just showed you. So for both of these we'll
5 be looking at that in that context.

6 We have a lot more work to do and
7 have with Roger and Eric some terrific
8 expertise on this committee relative to Omega-
9 3 fatty acids in health, and we're well along
10 with these evidence searches, et cetera.

11 One of the issues we want to look
12 at is plant versus marine sources of these
13 since the compounds are a bit different,
14 alpha-linolenic versus docosahexaenoic acid,
15 are obviously chemically different.

16 And we've had two terrific
17 Webinars, one from Professor Tom Brenna from
18 Cornell, one from Dr. Joseph Hibbeln from NIH,
19 on the effect of maternal diet on Omega-3
20 fatty acids on breast milk consumption and
21 infant health outcomes, and again, as I
22 mentioned in the discussions earlier, this is

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1 an impressive and growing body of literature
2 that I think should cause us pause to perhaps
3 even be more enthusiastic about fish
4 consumption, particularly in women of child
5 bearing ages.

6 Other research topics are what are
7 the health benefits related to consumption of
8 fats from specific foods, nuts, fish and
9 chocolate and health outcomes are some
10 specific -- this is kind of reminiscent of the
11 egg discussion relative to dietary cholesterol
12 because that was the inference from those, and
13 nuts, fish and chocolate obviously have some
14 interesting fatty acid compositions, but other
15 things as well.

16 And then to look at the genetic
17 polymorphisms affecting the association
18 between dietary components and plasma LDL
19 cholesterol, and looking at some of these
20 hyper and hyporesponder issues that we've
21 talked about. Certainly, there is some
22 evidence but whether or not these are ready

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1 for prime time and some other recommendations
2 is part of our deliberations.

3 We will be looking at some food
4 pattern modeling, looking at the impacts on
5 food choices and overall nutrient adequacy of
6 limiting cholesterol raising fat to less than
7 seven percent of total calories, and what is
8 the impact on food choices of the nutrients
9 and overall nutrient adequacy of limiting
10 cholesterol to less than 200 milligrams per
11 day.

12 I might say seven percent of
13 saturated fat calories and less than 200
14 milligrams per day of cholesterol are the
15 current recommendations for individuals with
16 coronary heart disease and with lipid
17 abnormalities. So these are more clinical
18 recommendations currently that we're looking
19 at the impact and the modeling effects that
20 they were put onto more population-wide
21 recommendations.

22 And then what is the impact of

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1 food choice and overall nutrient adequacy for
2 increasing Omega-3 fatty acids and look at
3 that in terms of broad health outcomes.

4 Just finally, I looked at about 25
5 public comments, and you can see what these
6 are related to saturated fat, cholesterol, and
7 stearic acid. Fatty acids probably is the
8 winner here.

9 About a third of the comments were
10 from students. Students, keep on sending
11 them. We enjoyed them. They were good
12 questions, and maybe don't send them to
13 everybody. I'm getting a difference in
14 consensus here, but you can send them to us
15 anyway.

16 But I wanted to congratulate the
17 students, and it's nice to know that young
18 people are listening to this process, and that
19 we're listening to you. I think that's the
20 other side of this. So those are my comments.

21 Questions? Mim.

22 MEMBER NELSON: This is Mim

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1 Nelson.

2 I'm wondering about this
3 recommendation, the implication about keeping
4 cholesterol to under 200 milligrams per day
5 when it seems like the preponderance of the
6 evidence especially with eggs which have
7 approximately, you know, 300 or so, that one a
8 day is okay. What's the rationale for keeping
9 the 200?

10 MEMBER PEARSON: Well, a couple of
11 things. Number one, I think the cholesterol
12 content of eggs has been going down so that
13 it's not 300 anymore, although I'm sure
14 there's probably some variability to that.

15 And, again, we're looking at
16 particularly for many subgroups, the
17 hyperlimidemic, the coronary disease
18 subgroups, and now it looks like the diabetic
19 subgroups, that would be the recommendation.

20 The 2005 recommendation was as low
21 as possible with 300 being the upper goal for
22 most individuals and 200 for these high risk

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1 subgroups, and the real suggestion would be
2 that the lower the better. There is, as
3 pointed out by the IOM report, since we
4 synthesize our own cholesterol, that there
5 really isn't any upper limit of normal that's
6 recommended, that's required. It's not a
7 minimum daily issue because of the synthetic
8 capacity that we have.

9 And given the general -- it
10 certainly looks like one egg per day on the
11 average is safe in healthy individuals. There
12 are these subgroups in which it is less so,
13 and so the recommendation would be to move
14 that down for them.

15 MEMBER PI-SUNYER: This is Xavier.

16 I wanted to ask you about this
17 replacement, five percent energy decrease of
18 saturated fat. You said that if it's replaced
19 with carbohydrate you get a lower HDL and a
20 higher triglyceride. Is that at that level of
21 five percent or is it a bigger replacement
22 that gives you that detrimental change in HDL

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1 and triglyceride?

2 MEMBER PEARSON: As we showed with
3 our NEL (phonetic) report, the evidence on
4 that is limited. I think it was in the range
5 of that. I have to go look at that, but there
6 was this recurrent theme with both
7 epidemiologic endpoints for modeling, as well
8 as randomized trial models with either lipid,
9 LDL specifically, or insulin sensitivity that
10 I think had some consistency with this five
11 percent difference, which conveniently looks
12 at the possible public health impact of going,
13 say, from 11 and a half to six and a half
14 percent, in other words, above 11 to less than
15 seven.

16 MEMBER PI-SUNYER: The reason I
17 mention that is because, you know, we're
18 talking earlier about energy density. We're
19 also going to talk about fiber. In a way if
20 you could substitute saturated fat with
21 carbohydrate, it will give you a higher energy
22 or lower energy density and a higher fiber

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1 intake. That would seem to be better than
2 substituting it with a high energy density
3 food like monounsaturates or polyunsaturates,
4 but I don't know what, you know, what the
5 detrimental part of doing that with regard to
6 HDL and triglyceride.

7 MEMBER PEARSON: Well, I think
8 others in the group can comment because we've
9 all been looking at these data, but in terms
10 of the beneficial effect of substituting out
11 saturated fat, the biggest benefit is
12 substituting MUFAs and PUFAs rather than
13 carbohydrates. So we are coming at it from
14 that side of the thing.

15 I found the energy density
16 discussions very interesting, and again, the
17 American Heart Association guidelines, the
18 2005 guidelines, again, were looking at not
19 commenting on a total fat, more of a 20 to 35
20 percent fat rather than getting into the very
21 low fat diets, which in fact do have effects
22 on HDL and triglycerides, which is

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1 carbohydrates, and whether looking at
2 healthful substitutions within those total fat
3 parameters as a way to particularly benefit
4 both lipid and insulin sensitivity parameters.

5 So that was the --

6 MEMBER SLAVIN: Can I jump in? I
7 feel like jeopardy. It's hard to get on the
8 button here. So I've got to get faster on the
9 draw.

10 (Laughter.)

11 MEMBER SLAVIN: But the soluble
12 fiber stuff on HDL actually keeps HDL up. So
13 I think with carbohydrate it's not -- a lot of
14 the epi data makes carbohydrate look like the
15 bad guy while a lot of the feeding stuff,
16 depending on which carbohydrate you're taking,
17 HDL actually goes up. So I'd want to put in a
18 plug here.

19 MEMBER PEARSON: It's an important
20 concept, and it's totally analogous to mono
21 and polyunsaturated fats versus saturated
22 fats, which we're all bedeviled. There's

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1 total fat and then we got into these very low
2 fat diets and watching our HDL go. So it's
3 absolutely analogous. It has to do with
4 educating about which fat and which
5 carbohydrate rather than they're all good or
6 they're all bad.

7 MEMBER SLAVIN: I wanted to follow
8 up on Mim's just because of the egg, because I
9 think for high quality protein I'm with kids
10 and getting better diets into people with
11 lower calories. I'm just really big on eggs
12 and protein qualities.

13 So making sure we don't let
14 cholesterol make the decision here.

15 MEMBER PEARSON: But also to
16 remind you that the cholesterol is in the yoke
17 of the egg, and the protein is in the white,
18 and you can actually do something about that.

19 MEMBER SLAVIN: Well, there's
20 actually protein in the yoke also, and there's
21 lecithin and choline and other things we're
22 trying to get into the diet.

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1 MEMBER FUKAGAWA: This is Naomi.

2 And I think -- sorry, Larry.

3 (Laughter.)

4 MEMBER FUKAGAWA: This is Naomi
5 Fukagawa.

6 So I may be eating the wrong mix
7 of fatty acids since my reaction time was
8 rather slow, and I'm going to admit --

9 (Laughter.)

10 MEMBER FUKAGAWA: -- that my
11 memory may be failing me, but getting back to
12 the proposed conclusions for the *trans* fatty
13 acids, my understanding was that we had
14 concluded that ruminant *trans* fats in the
15 amount that is presently consumed is not
16 problematic and does not need to be a target
17 for the total dietary change, and because --

18 MEMBER PEARSON: That really
19 wasn't our question. We could probably
20 extrapolate from that. Our question was did
21 it appear that ruminant *trans* fatty acids were
22 acting differently than industrial *trans* fatty

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1 acids, and our conclusion, at least with Grade
2 level of evidence was it did not appear so.

3 MEMBER SLAVIN: At high dose.

4 MEMBER PEARSON: At high dose,
5 yeah.

6 MEMBER SLAVIN: But I thought that
7 it was important to qualify because *trans* fats
8 do come from a natural source that also has
9 important other nutrients.

10 MEMBER PEARSON: And that's why I
11 put the level of consumption on there. But
12 one could perhaps -- I don't know how -- you
13 can obviously see how industrial *trans* fatty
14 acids could be put in high amounts, but
15 certainly if those similar levels of ruminant
16 ones were used, I think the suggestion is they
17 would act the same as industrial ones.

18 But, again, as I put it in the
19 levels of exposure, the natural occurring
20 ruminant ones, which is 0.5 percent or less of
21 calories, is a small amount. It's interesting
22 that there were a number of comments in the

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1 comment about, you know, should we -- you
2 know, is 0.5 percent -- maybe we want to go
3 even below that, and this was a topic of many
4 other comments, and this may not be possible.
5 It's just like many things, that the lower you
6 go the harder it is to get rid of everything.

7 MEMBER SLAVIN: But I guess that's
8 why this is important from the context of not
9 confusing the consumers, because you know, we
10 don't want to make them afraid of the whole
11 food that's available in our supply, and I
12 think it's very important that we balance our
13 message from that perspective.

14 MEMBER PEARSON: But our question
15 was really addressing a different -- you know,
16 at the same level of perhaps your population
17 would be consuming these to increase their
18 risk. Are these two acting biologically the
19 same?

20 And apparently the look is that
21 they are.

22 MEMBER APPEL: Yes, very

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1 interesting, Tom. I had some questions/issues
2 about the cholesterol conclusion and
3 discussion. One is -- I can rattle them off
4 and then you can -- so when it comes to
5 clinical trials that don't see an outcome, you
6 know, was there enough power? I mean, you
7 know, some of these studies, I think, are
8 pretty small, you know. So that's sort of one
9 question.

10 But --

11 MEMBER PEARSON: You mean the
12 RCTs?

13 MEMBER APPEL: The RCTs, yeah. I
14 know you didn't go into a lot of detail on it,
15 but I think that's an important issue.

16 The second is shouldn't we take a
17 look at the total amount of cholesterol in egg
18 eaters and non-egg eaters and just get an
19 understanding of where cholesterol is coming
20 from?

21 And this is related to my third,
22 which is at the conclusion it's sort of funny.

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1 We have a very specific food group where
2 there's a conclusion, and I'm wondering
3 whether the conclusion should be more on
4 cholesterol and then the implications might be
5 that, you know, one egg a day for people who
6 are otherwise not consuming a large amount of
7 cholesterol, you know, is okay, but right now
8 it is really an egg conclusion which I think
9 is sort of funny.

10 MEMBER PEARSON: You know, I think
11 you raise several good points. Number one, as
12 pointed out, not that many years ago I know I
13 think it was the NHANES from one of the 1990s
14 or something had about 38 percent of dietary
15 cholesterol from eggs.

16 MEMBER APPEL: Yes.

17 MEMBER PEARSON: That apparently
18 has now fallen to 25 percent or less. So the
19 point you're making about looking at total
20 dietary cholesterol consumption is
21 increasingly important, but if, in fact, eggs
22 are only a quarter of the dietary consumption,

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1 then to say that one egg a day, and if we're
2 shooting at 300 to say nothing about 200,
3 obviously it doesn't add up because if you're
4 eating one egg a day and that's a quarter of
5 your -- and you've still got --

6 MEMBER APPEL: You still have the
7 remaining. You're well over.

8 MEMBER PEARSON: That's my point.
9 That's my point.

10 MEMBER APPEL: That's why I'm
11 thinking about the implication because I think
12 it's a little bit more nuanced, you know.
13 Well, if you decide to eat an egg a day, but
14 hopefully you're not eating scallops and
15 shrimp for the rest of your -- yeah.

16 MEMBER PEARSON: And we've been
17 very impressed with that. I was very
18 impressed by the changes in the fatty acids
19 and cholesterol content of many foods over
20 time as they've been kind of engineered out or
21 brought to the consumer with lower levels.

22 So some of the old consumption

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1 data, I think, has to be, you know, re-looked
2 at.

3 MEMBER APPEL: We got that for
4 salt, you know, and I think we got the tables
5 presented, and this might be one nutrient
6 where you want to see where the cholesterol is
7 coming from, you know.

8 MEMBER PEARSON: I'm not sure I
9 answered all of yours.

10 MEMBER APPEL: Yeah, the other one
11 was the RCTs. You know, I was thinking about
12 this. We're going through this really
13 quickly, you know, five negative RCTs. The
14 easiest way to get a negative RCT is just have
15 an underpowered study, you know.

16 So I just wonder are these decent
17 size where you can actually, you know, say
18 that we had adequate powers so that we didn't
19 miss clinically relevant change.

20 MEMBER PEARSON: Many of them were
21 small and relatively short term, and industry
22 funded, and also may not have had as a primary

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1 hypothesis some of the specific lipid
2 endpoints we are looking at.

3 MEMBER PEREZ-ESCAMILLA: This is
4 Rafael.

5 At the last Society for
6 Nutritional Education meeting in New Orleans
7 there was a very interesting talk about the
8 labeling of *trans* fats in foods, and the whole
9 talk was about zero is not zero, and it's the
10 issue that brought us that says zero *trans*
11 fats and half, partially hydrogenated oil;
12 they still have *trans* fats. And they gave us
13 a number of examples as to how you could end
14 up ingesting a good amount of *trans* fats if
15 you consume, you know, not too many servings
16 of those products.

17 So I think that situation deserves
18 to be addressed and corrected because it is
19 very misleading for the public.

20 MEMBER PEARSON: This came up with
21 several commenters, and I guess I would take
22 their point. Although at very low levels you

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1 get into all sorts of measurement issues and
2 certainly getting it lower than that, it's
3 like an environmental pollutant. You know,
4 the first half is easy to get rid of. The
5 second half gets really expensive.

6 MEMBER CLEMENS: Rog here.

7 That's an excellent comment,
8 Rafael, in the SNE, and we had a lot of
9 comments from the public on that, I believe if
10 I remember my food law correctly that the FDA
11 has defined acidic acid as a *trans* fat which
12 occurs naturally, of course, but CLA is not
13 considered a *trans* fat from the FDA's
14 perspective, and there are 13 isomers of CLA,
15 and as we know, when we take in those isomers
16 either through beef or from milk, we actually
17 can summarize those either to assist or
18 transform.

19 So at what point do you want to
20 include those isomers in terms of labeling?
21 Right now the FDA does not do that.

22 MEMBER PEREZ-ESCAMILLA: I think

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1 that issue is about products that leave
2 partially hydrogenated oil as an ingredient
3 and they claim it has zero *trans* fats.

4 MEMBER NELSON: Sorry. Go ahead.

5 MEMBER PI-SUNYER: This is Xavier.

6 I was kind of depressed with your
7 statistics about no change over all these
8 years, and you know, I don't know if that's
9 due to the lipid skeptic literature that's out
10 there or very poor translation of our message
11 or what, but it seems like a number of
12 different dietary guidelines have come up with
13 recommendations that have been totally not
14 followed by the American public.

15 MEMBER NELSON: Yes, but, Xav,
16 this is Mim.

17 I would say if you look at the
18 supply of foods, that it's completely the
19 supply chain has changed. We have more meat.
20 We have more -- I mean, the foods that
21 contribute to saturated fat, the supply is
22 just different.

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1 So I would say it's not about the
2 personal, you know, choice pieces. It's
3 simply our food supply has changed to mimic
4 that, including the increased caloric intake
5 which you had on the bottom there.

6 MEMBER RIMM: Yeah, this is Eric
7 Rimm.

8 To add to that, 15 or 20 years ago
9 we told everybody to eat a low fat diet, and
10 I'm not sure we were giving them the right
11 advice. I don't know if that drove up the
12 heart disease rate, but I think it certainly
13 didn't help driving them down.

14 MEMBER PEARSON: And it didn't
15 help our diabetes epidemic.

16 MEMBER APPEL: I'm just putting
17 things in perspective though. Do you think
18 the current guideline, less than ten percent
19 saturated fat -- okay. So we've been at 11
20 percent then for several years, which is not
21 too far from where we wanted to be.

22 Now, the American Heart

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1 Association in 2006 dropped it to seven
2 percent. So compared to that we are worse
3 off, you know, but that's a migration creep in
4 terms of standard. That just occurred a few
5 years ago.

6 CHAIRPERSON VAN HORN: I think the
7 other thing that needs to be recalled here is,
8 you know, in the '70s our average American
9 fat intake was about 42 percent of calories.
10 So, you know, any way you look at it as Tom
11 pointed out, we're now hovering around a 33,
12 34 percent. So, you know, that shift has
13 already occurred.

14 But the other thing that I think I
15 would like us to go back to because of our
16 ongoing interest in obesity, and I think we
17 need to remember that we really don't know at
18 this moment the risk-benefit in terms of
19 weight loss versus monounsaturated fat
20 increase in terms of impact on HDL. We know
21 that weight loss in an obese person raises
22 HDL. We also know that shifting to a

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1 monounsaturated source of fatty acids protects
2 HDL.

3 So you know, the question overall
4 is in an overweight person I think most of the
5 people around this table would say, you know,
6 first and foremost lose weight, and as we've
7 been saying earlier today, you know, if that
8 takes a total fat intake that is 28 percent of
9 calories or something of that sort in order to
10 achieve that lower energy density that we're
11 talking about, that for that individual may be
12 the right approach.

13 I think the problem is that we do
14 get to a point where one size does not
15 necessarily fit all, and the weight issue
16 sometimes trumps other things in terms of
17 trying to make up the qualitative decisions
18 about that.

19 Tom, do you want to comment?

20 MEMBER PEARSON: Linda, there's
21 some very good evidence to say what you say is
22 true and that the Minnesota heart study showed

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1 some modest improvements in total saturated
2 fat and cholesterol levels and the change in
3 the extant scores at a time in which there was
4 absolutely no change in serum cholesterol. It
5 went up a little bit, and it was a time in
6 which their calories per day on the average,
7 their body mass index and all the indicators.

8 So it's a very good evidence that
9 weight reduction, prevention of obesity has to
10 be part of this whole thing.

11 MEMBER RIMM: This is Eric Rimm.

12 Just to echo again what you said,
13 Linda, I think it is an important point, and
14 sort of going back on -- thanks for bringing
15 this up -- but going back on what Frank Sacks
16 spoke about before, the sort of fluctuations
17 of fat, carbohydrate and protein really don't
18 make that much difference. It's really about
19 losing weight.

20 So I don't think there's one exact
21 diet that's going to drive weight down. I
22 think if you're holding fat constant, clearly

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1 switching the type of fat you're getting is
2 going to be beneficial, but the most important
3 thing is to drive weight down.

4 MEMBER NELSON: This is Mim.

5 Sorry to go back to this
6 cholesterol question, but it's really -- I
7 don't know -- it's puzzling me. So are we
8 talking that we actually are going to change
9 what was in the 2005, you know, from the upper
10 limit of 300? We're going to say it's going
11 to be 2000? Because I just am not seeing the
12 evidence there, and I'm concerned if we're
13 going to change it that if we don't have
14 strong evidence it concerns me.

15 MEMBER PEARSON: The
16 recommendation for the 2005 was that the
17 dietary cholesterol should be as low as
18 possible, and the IOM report is also
19 corroborated with that, having to do with the
20 fact that we could synthesize what we need.
21 It's not an essential compound.

22 And so what the spectrum is, in

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1 addition to coronary patients, patients with
2 high LDL, now it would certainly appear that
3 people with diabetes, in fact, do have
4 evidence that their cholesterol level of 200
5 or a reduction in a consumption -- again,
6 there's different pieces of evidence -- do
7 benefit from a lowering of their dietary
8 cholesterol.

9 So it gets to the situation about
10 how many of these subgroups do you want to
11 have before it becomes the population
12 recommendation.

13 MEMBER NELSON: I thought it was
14 more, you know, our guidelines were more
15 focused towards the sort of general healthy
16 population and no subgroups.

17 MEMBER PEARSON: For prevention.

18 MEMBER NELSON: For prevention. If
19 everybody is fine with that, I am. I'm
20 worried about the eggs. There's just so many
21 good things in them, and you know, the other
22 conclusion was that one egg a day is okay,

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1 which may be in conflict with -- I know that
2 cholesterol has been coming down in the eggs,
3 but we're saying in one that one egg a day is
4 okay and in the other we're saying it needs to
5 be under 200.

6 MEMBER SLAVIN: This is Joanne,
7 too.

8 I kind of want to follow up with
9 Mim because if 300 is kind of the general
10 accepted everywhere else, if we're moving to
11 200, I think we need more of a vote and more
12 data than I've seen to feel comfortable with
13 that.

14 MEMBER NICKOLS-RICHARDSON: and
15 this is Shelly.

16 I just want to jump on that
17 comment that what if what our dietary intake
18 data are showing us, what if that level is as
19 low as possible when we talk about whole
20 foods, whole diet, and so what else can be
21 done then if it's that tradeoff between the
22 other fatty acids rather than the cholesterol

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1 piece?

2 Just in terms of the volume of
3 work, this may be one of those modeling
4 questions that we could push to another time
5 so that if we believe that what the data are
6 showing is that it's really not perhaps this
7 cholesterol piece, that's something that could
8 be held for a later point and perhaps not done
9 now because I think in terms of what we know
10 about those sources of cholesterol animal
11 products and what that might do to all of the
12 other nutrients, and we think about calories
13 in the context of obesity and everything else,
14 but wanting a nutrient rich diet, then I'm
15 concerned about changing sort of the animal
16 based foods and the other nutrients that those
17 provide.

18 MEMBER PEARSON: Yeah, we kind of
19 look at it the other way, and this should be
20 one that we'd be very interested in taking a
21 Grade 2 evidence. I mean, we never certainly
22 thought that this was Grade 1 evidence. I

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1 mean, we're essentially agreeing with you that
2 there really are some holes in this data,
3 particularly in the panoply of industry
4 supported trials, some trials that have a
5 vested interest in foods that contain
6 cholesterol.

7 And so the modeling, on the other
8 hand, would really be helpful in deciding how
9 aggressively we'd want to be with that. So we
10 were looking at this -- at least I was looking
11 at this a little bit differently because this
12 is the kind of thing we would want to model
13 because what are the other issues, the
14 competing benefits and risks that we'd have.

15 MEMBER APPEL: This is Larry.

16 I don't really understand what is
17 recommended in 2005. I have the report here.
18 Now, I know the IOM said as low as possible.
19 They didn't give an upper limit. In 2005 we
20 said it was based on LDL cholesterol. For
21 those less than 130, less then 300 milligrams,
22 less than 300. For those with elevated LDL

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1 greater than 130, less than 200.

2 So was there a change between --

3 MS. McMURRY: And the government's
4 dietary guidelines on page 30 -- this is
5 Kathryn McMurry -- recommend consume less than
6 300 milligrams per day of cholesterol for the
7 general population recommendation.

8 MEMBER APPEL: Okay. So it's not
9 as low as possible then.

10 PARTICIPANT: McMurry. I think, you
11 know, once again -- and that's a very good
12 example that one size doesn't fit all -- I do
13 think there's some opportunity here for
14 tweaking some of these levels.

15 MEMBER VAN HORN: No one is
16 suggesting that dietary cholesterol is not
17 atherogenic. I mean the Keys and Hegsted
18 scores still work. I know they do, and in
19 fact, you know, looking at dietary
20 cholesterol, saturated fat, those are the two
21 most atherogenic aspects of our diet.

22 But in an individual who is not

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1 already at risk or have an elevated LDL
2 cholesterol, I think you know there is some
3 wisdom in some of these previous
4 recommendations that allow a little discretion
5 in terms of the nature of the individual with
6 some judicious approach to exactly what gets
7 recommended based on a person's risk status.

8 So, you know, I think that perhaps
9 the best thing we can do is not necessarily
10 rigidly, you know, decide one or the other,
11 but you know, use the same sort of range
12 concept based on risk.

13 MEMBER PEARSON: And I guess the
14 evidence base we thought did extend to people
15 with diabetes in terms of the 200, as well as
16 those individuals with cholesterol
17 abnormalities, and establish cardiovascular.

18 PARTICIPANT: Right, and once
19 again, this could be a source of
20 recommendations for the future. I think, you
21 know, the whole issue about quality protein in
22 children and, you know, quality protein,

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1 animal versus vegetable protein and the
2 discussion we were having yesterday, you know,
3 those are all questions that we still really
4 haven't adequately studied to be able to
5 determine what's the best mix in terms of
6 coming up with the most nutritious, but also
7 least atherogenic model.

8 MEMBER WILLIAMS: I just wanted to
9 mention as far as expressing cholesterol in
10 terms of milligrams per 1,000 calories, when
11 you think of very young children, you almost
12 would eliminate eggs from the diet of
13 preschool children if you express it based on
14 1,000 calories.

15 Also, one other comment about
16 taking out *trans* fats from foods. In some
17 cases they've been replaced by palm oil and
18 some other oils that are higher in saturated
19 fat, and what does that do to our consumption
20 of saturated fats?

21 MEMBER RIMM: Of course that would
22 be an issue if it was a tremendous amount of

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1 fat that was put in because, as we've said,
2 it's better to have mono and polys than it is
3 to have sat, but sometimes a very small amount
4 of sat is put in just to make the product hard
5 instead of soft.

6 So I think it will obviously
7 depend on the product, but if it's a very
8 small amount, a very small amount of saturated
9 fat, I think, is not that much to give up if
10 we can get rid of the hydrogenated oils.

11 Sorry. That was Eric Rimm.

12 CHAIRPERSON VAN HORN: Anything
13 else? Tom?

14 All right. Well, very
15 interesting, very worthwhile, and thank you
16 for that excellent review, and lots of
17 questions yet to discuss.

18 I think we'll now go right ahead
19 and move into ethanol, and the chair of that
20 group is Eric Rimm.

21 MEMBER RIMM: Alphabetically we're
22 going from eggs to ethanol.

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1 Thank you, Linda.

2 I wanted to first start by
3 acknowledging my colleagues, Larry Appel, Tom
4 Pearson and Naomi Fukagawa, and the great help
5 that we've received from HHS and USDA from
6 Rachel Hayes, Jean Altman, Patricia Guenther,
7 and Shirley Blakely.

8 So the topics I'd like to address
9 today start out with I think sort of a helpful
10 review from an updated analysis from NHANES on
11 average beverage consumption and alcohol
12 beverage consumption, and then go on to talk
13 about a few of the questions we've addressed,
14 ethanol weight gain, ethanol dementia, ethanol
15 and cardiovascular disease, and then highlight
16 some of the remaining research topics.

17 So to get at some of the issues
18 related to what we're drinking in America,
19 Patricia Guenther and her team, Shanty and
20 Joe, have looked at data from NHANES from a
21 variety of sources. Some of these are from
22 24-hour recalls. Some of these are from the

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1 alcohol youth questionnaire, and some of these
2 are from food frequency questionnaires that
3 are used depending on the year and the time of
4 the visit, and some of the questions are
5 listed here.

6 How many adults drink alcoholic
7 beverages? And to look at that, we'd like to
8 sort of address the question of how many
9 adults drink beer, wine or distilled spirits
10 on a given day; how many adults drink any
11 alcoholic beverage at least once in a year.

12 And also we wanted to ask the
13 questions of how much alcohol do adults
14 consume, and that is what is the distribution
15 of alcoholic beverages intake on a given day,
16 and some of that speaks to the caloric content
17 of the beverage since there is a different
18 caloric content of the beverages, and what is
19 the distribution of average daily alcoholic
20 beverage consumption, and what is the
21 distribution of alcoholic beverage consumption
22 by adults on days that they drink.

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1 So let's look at some of that
2 data. It really, I think, helped us to think
3 a little bit more deeply about the questions
4 we want to ask and the guidance we want to
5 give. So let's start out with the first
6 question, and this one is really just to look
7 at distribution of alcohol. It's a little
8 deceiving because this is not on average how
9 much the people consume, but this is on any
10 given day. So this is from a 24-hour recall.
11 So naturally most people don't drink every
12 day. So even though there may be moderate
13 drinkers among here, some of them may drink
14 nothing on a given day.

15 So this is just in a given day
16 from NHANES between 2003 and 2006, what were
17 people drinking? So on a given day 32.8
18 percent of men will drink an alcoholic
19 beverage, and 17.4 percent of women will
20 drink.

21 And here is the distribution to
22 show that it is slightly different by gender.

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1 I think much of this has been published over
2 the years in the literature, and obviously
3 industry knows about this from classic sort of
4 disappearance data, but you can see that men
5 drink more beer than women.

6 And you can also see -- I wanted
7 to break this out because I was a little bit
8 concerned about caloric content because beer
9 in general will have 30 or 40 percent more
10 calories than wine or distilled spirits,
11 unless it's light beer, and also I wanted to
12 make the point that not all distilled spirits
13 necessarily is consumed by itself. The last
14 column shows distilled spirits as a mixed
15 drink, and so somewhere in the range of 60 to
16 80 percent of distilled spirits are consumed
17 with something else which could also contain
18 calories.

19 So if our concern really is
20 alcohol and alcohol containing beverages and
21 weight gain, we wanted to look at the
22 distribution of where the calories are coming

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1 from.

2 So maybe something that you have
3 been maybe more accustomed to seeing as sort
4 of on average how many people drink in this
5 country, and this is the data based on alcohol
6 use questionnaires where individuals were
7 asked have you consumed any alcoholic beverage
8 at least once in the past 12 months. So this
9 really is the top end estimate. This is for
10 all adults 21 and over. For men it's 76.3
11 percent and for women it's 65.3 percent, and I
12 believe -- I can't see because the arrow is in
13 my way -- but I believe this is 2003 to 2006.

14 Yes, so this is the most updated data.

15 So now going forward we're really
16 actually more concerned about patterns of
17 consumption this time around. We felt that
18 there is enough data in the literature to
19 address patterns as opposed to just average
20 consumption.

21 We wanted to break out on those
22 days that individuals drank how much were they

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1 actually drinking. So hopefully you can see
2 this, but the blue -- I'm going to point to it
3 because I know that someone over there has to
4 point to my pointer -- the blue is 65.9
5 percent. That means on any given day 65.9
6 percent of men don't drink, but if they are
7 drinking, how much do they drink?

8 And you can see as you go around
9 the pie 8.3 percent drink one drink, 6.8
10 percent drink two drinks. So this would be
11 the cutoff for the current U.S. dietary
12 guidelines. On any day drink two drinks a day
13 or less for men.

14 So that means that 19.0 percent of
15 men are drinking in excess of the dietary
16 guidelines on any given day, and this pie
17 that's broken out here shows how much they are
18 drinking. So 5.8 percent are drinking three;
19 4.1 percent are drinking 4; five, six, seven,
20 3.6 percent are drinking eight-plus drinks per
21 day.

22 So I didn't mean to present this

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1 as a "wow" factor. Obviously alcohol abuse is
2 a problem in this country, and a significant
3 percentage of the population, and this, of
4 course, is people who participate in NHANES
5 and people who happen to be drinking on the
6 day that they were asked.

7 So it does speak to the issue of
8 patterns and maybe giving a dietary guideline
9 based only on average may be more difficult
10 for some people to incorporate into their
11 thought process about drinking patterns.

12 So let's look at the data for
13 women. Again, the format is very similar. On
14 any given day about 81 percent -- thank you.
15 Oh, you're beating me to pointing -- about
16 80.9 percent of the women don't drink. Ten
17 percent drink one drink. So those are the
18 women that would drink within the current
19 dietary guidelines if not more than one drink
20 per day.

21 It also means that nine percent of
22 women on any given day are drinking in excess,

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1 but you can see that nine percent breaks down
2 to 3.1 percent drinking two, 2.1 percent
3 drinking three, and so on, four, five and six-
4 plus.

5 Again, there is clearly an issue
6 of excess consumption in a small percentage of
7 the population, but we would still consider
8 that a significant percentage of the
9 population, given the detrimental health
10 effects of excess alcohol consumption.

11 So I guess that's the basis for
12 some of our further work, is trying to
13 understand issues related to drinking
14 patterns.

15 So I'm looking at more of on an
16 average. So if individuals are asked how much
17 alcohol do adults consume on average over the
18 course of a year, you can see that people
19 report more of like what you expected me to
20 show, is that 23.7 percent of men don't drink.
21 Sixty percent of men drink on average one
22 drink a day. Seven percent drink on average

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1 two drinks a day, and 8.6 percent drink on
2 average above the current U.S. dietary
3 guidelines of two drinks or less per day.

4 This, again, is updated data from
5 Patricia, Shanty, and Joe from the '03 through
6 '06 NHANES analyses.

7 For women you also see the same
8 thing. On average, 34.7 percent don't drink;
9 61.5 percent drink one drink a day; and this
10 would be, therefore, within the U.S. dietary
11 guidelines, and 3.8 percent drink on average
12 in excess of the dietary guidelines.

13 So now the more challenging issue
14 really is related to patterns of consumption
15 and, I guess, binge drinking, and so what we
16 tried to -- we're sort of teasing the data
17 apart in three different ways and maybe we're
18 pulling too hard, but I think it's useful to
19 help us think about how we would put forward
20 the guidelines.

21 And so this is on the days that
22 men drink, how much do they drink, and this is

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1 not just on the day that NHANES happened to go
2 there, but this is more based on average how
3 much do they drink on days that they drink.

4 So you can see this is number of
5 drinks consumed on those drinking days, and
6 the blue bar is total adults, and we broke it
7 down by age just to show you that clearly
8 there's a difference. As men age, their
9 amount of excess consumption, four, five, and
10 six drinks on a drinking day, is much less
11 than the men that are 21 to 64.

12 So the point here is that the
13 current dietary guidelines suggest that men
14 should not drink more than two drinks a day.
15 So if you add it up, you can see that the blue
16 bars add up to more than 50 percent of men on
17 days that they drink, drink in excess.

18 Now, we don't know if this is just
19 one day a year or if this is 364 days a year,
20 but we do know that there clearly is excess
21 drinking based on the current U.S. dietary
22 guidelines, and the definition of binge

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1 drinking accepted in the literature is five
2 drinks a day in a session for me, five or more
3 drinks per day and four or more drinks a day
4 for women.

5 So, again, if you look at women,
6 you see the similar type of distribution, that
7 on days that they drink, how much do they
8 drink, and here, once again, you can see that,
9 again, the U.S. dietary guidelines for women
10 right now says one drink a day or less. So
11 that's 45 percent. So more than 50 percent of
12 women on days that they drink drink in excess
13 of the U.S. dietary guidelines.

14 All right. So, you know, this
15 does pose a dilemma for us. I know that we've
16 already talked about sodium where 97 percent
17 of kids, I think, were over, in excess of the
18 sodium upper limit. So it does also point to
19 the fact that based on our most up to date
20 data when men and women drink on days that
21 they drink, more than half of them drink in
22 excess of the dietary guidelines.

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1 So I guess our main question still
2 remains and one that I'm not going to answer
3 today but one that I look to the committee for
4 some insight: is it more important to provide
5 a recommendation for average consumption or is
6 it more important to provide a recommendation
7 for pattern of consumption?

8 And it has been over the last 25
9 or 30 years that the U.S. dietary guidelines
10 has stuck with the one a day for women and two
11 a day for men, and it was not written as
12 average. It may have been implied, but
13 essentially it says the cutoff is one a day
14 for women and two a day for men.

15 So here's what I see are the three
16 possible options for moving forward on trying
17 to decide how to define alcohol consumption.
18 One is as this committee in 2005, really,
19 again, it's not directly written that way, but
20 it is implied based on summarizing the data at
21 the time. The implicit recommendation was
22 that the average consumption -- that

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1 consumption should be on average two per day
2 for men and one a day for women. That could
3 be drinking on four days per week, and then
4 having three to four on those days. It could
5 be a woman drinking three days a week and
6 having two drinks on those days instead of
7 having one per day.

8 However, it's really, I think,
9 more implicit in the dietary guidelines for
10 Americans. Once the technical report was
11 translated into policy, it really had a daily
12 limit of two per day for men and one per day
13 for women.

14 So it's not a complete disconnect,
15 but the bulk of the epidemiological evidence
16 that led to the first guideline is based all
17 on average consumption. There were very few
18 papers published on patterns of the
19 consumption before 2005. There was some, but
20 not very many, and so most of them are based
21 on average consumption, and since most people
22 don't drink every day, there obviously was

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1 some averaging going on.

2 So our final option is to look at
3 what NIH or NIAAA has put forward in their
4 rethinking drinking, which is something
5 they've just put out in the last month, which
6 I'll show you in a bit which really gets away
7 from average and sort of speaks to daily
8 limit, but actually gives two separate limits.
9 One is a weekly limit and one is an explicit
10 cutoff for not having excess drinking, no
11 binge drinking.

12 So just to show you a little bit
13 more about that since I think it is an
14 interesting approach, it's an approach that
15 other countries have used, but it's one that
16 the dietary guidelines has not used in the
17 last 25 years that they've been published.

18 This is what NIAAA currently has
19 in that document. Interestingly enough, this
20 is about a 20-page document that you can find
21 on their Website. I think it's actually
22 rethinkingdrinking.gov. Also it's a PDF that

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1 you can download, and this actually is meant
2 to help people reduce excess consumption. It's
3 really a document all about more in
4 identifying individuals with problems and
5 trying to get them down to what they call low
6 risk drinking, and low risk drinking is broken
7 up into two parts. If you start out with the
8 per week part, it says for men they should
9 drink no more than 14 drinks per week, and for
10 women they should drink no more than seven
11 drinks per week.

12 If you've done the math, you can
13 say on average if you have two drinks a day
14 that's 14 drinks for men and one drink a day
15 is seven for women.

16 The difference here is that what
17 they are saying is on any single day you can
18 drink up to the cutoff for binge drinking,
19 which is no more than four drinks on any day
20 for men and three drinks for women.

21 Now, this is obviously a little
22 bit more liberal and gets several people

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1 around the table, including my colleague Larry
2 Appel, who threw me under the bus before,
3 since he's usually the one drinking in excess,
4 but --

5 (Laughter.)

6 MEMBER RIMM: -- but at this -- I
7 warn people I will get you back. We're
8 friends. I'm just kidding. I've never seen
9 him drink more than two drinks in any one
10 sitting.

11 But it is a little bit more
12 liberal in the amount of alcohol that could be
13 consumed in any one day, although it clearly
14 has the same upper weekly limit, and maybe if
15 we are thinking about dietary guidelines for
16 alcohol, we should be thinking not on a daily
17 basis, but more on a weekly basis only because
18 people don't drink every day.

19 So our question going forward was:
20 is there evidence to support this? And that's
21 why we went to the evidence libraries, to try
22 to see if there was enough data to support

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1 either the guidelines that were from last time
2 of no more than one or two for women and men
3 or to support this NIAAA.

4 Now, there's a lot more verbiage
5 which I won't read to you in detail, but there
6 is some scientific support that they provide
7 here from NIAAA's own study saying that in
8 their nationwide survey of 43,000 U.S. adults,
9 only about two in 100 people who drank within
10 this guideline were not truly at low risk,
11 which means that they were at high risk. Even
12 though they were drinking within this
13 guideline, they were probably drinking in
14 excess or were alcoholics and could not stop
15 drinking or had alcohol addiction problems.

16 So that's a little bit of
17 background. There is not a lot of other
18 background that is printed within this
19 rethinking drinking, and again, the focus of
20 the rethinking drinking was on getting people
21 to reduce their alcohol consumption.

22 So we went to the evidence library

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1 and the first thing we wanted to look at was
2 ethanol and weight gain. This was addressed
3 in the 2005 dietary guidelines at the time.
4 There wasn't enough evidence. There's only a
5 few cross-sectional studies and maybe one or
6 two prospective studies, and I didn't think
7 the cross-sectional studies were necessarily
8 worthwhile in pursuing further only because of
9 reverse causation issues.

10 So we tried to focus on
11 prospective studies in the randomized clinical
12 trials to look at the effect of ethanol on
13 weight gain.

14 So we went back to 1994. That was
15 based mostly on, I think, our expert opinion
16 on when the studies first began in terms of
17 these large scale observational studies. We
18 focused on adults, obviously and had these
19 MeSH terms, and again focused only on
20 observational studies and randomized clinical
21 trials.

22 I won't go through all of them

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1 now. There were eight studies, seven modestly
2 sized to very large size prospective
3 observational studies, one randomized clinical
4 trial. Obviously it's a randomized clinical
5 trial. It's not going to be long term because
6 they were looking at alcohol.

7 It was a weight loss trial, where
8 they fed individuals either alcohol or
9 isocaloric amounts of fruit juice. Not
10 surprisingly, if it's isocaloric both sides
11 lost about the same amount of weight.
12 Interesting enough actually, the group that
13 was randomized to alcohol lost a little bit
14 more weight, but the study is relatively
15 small. So that difference wasn't significant,
16 but it's a weight loss study. It worked. I
17 wouldn't necessarily use alcohol as a device
18 in a weight loss study, but that's the only
19 randomized clinical trial on the topic. I
20 know editorial opinions will be further put
21 forward.

22 Overall, conclusions, and I think

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1 it was actually pretty consistent across the
2 board, which is why we gave it a Grade 2, is
3 that the evidence predominantly from
4 observational prospective studies suggests
5 that among the free living populations
6 moderate drinking is not associated with
7 weight gain.

8 Now, you know, I think Larry was
9 very helpful in crafting this. I think we
10 have to stand back and realize that these
11 observational studies were among free living
12 populations, where the observational studies
13 tried to account for their diet and tried to
14 account for the difference in exercise
15 patterns and tried to account for the
16 differences in smoking and, you know, didn't
17 find that the individuals who drank alcohol
18 gained weight.

19 We didn't really find sufficient
20 evidence to determine the relationship of
21 drinking patterns or frequency of consumption
22 to weight gain, not enough of the studies

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1 address that. Almost all of them were based
2 on average consumption.

3 However, in the few studies that
4 had sufficient power, there was clearly an
5 association between heavier consumption, and
6 that means consuming over two drinks a day on
7 average. There was an association between
8 heavy consumption and weight gain.

9 The next topic we wanted to
10 address was cognitive function. This is one
11 that wasn't touched in the 2005 dietary
12 guidelines, and I felt that there had been a
13 sufficient amount of data both pro and con for
14 the effects of alcohol on cognitive function,
15 and in this case we looked at among person --
16 the question was: among persons who consume
17 alcoholic beverages, what is the relationship
18 between patterns of alcohol intake and
19 cognitive decline with age?

20 I should point out that this was
21 not related to the acute effects of ethanol on
22 cognitive function or anything related to

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1 acute brain damage. This was really looking
2 at those studies that looked at long-term
3 change in cognitive function typically
4 associated with age.

5 So again here, some of the first
6 studies on this started to come out in the
7 late 1990s. So it was a little bit easier for
8 us to go back and capture all of the evidence.
9 Again, we focused here on adults and we use
10 the standard MeSH terms for cognitive
11 impairment.

12 There were a lot of studies here,
13 and I think that's one of the reasons why I
14 wanted to look at the data. Twenty-four
15 studies, one was a meta-analysis of the
16 studies; 21 of them were prospective cohort
17 studies; two were case controlled studies; and
18 again, we eliminated the cross-sectional
19 studies from this for reasons related, again,
20 to reverse causality.

21 So our conclusion from this,
22 again, it's Grade 2 evidence. The evidence in

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1 observational prospective studies suggest that
2 compared to non-drinkers, individuals who
3 drink moderately have reduced cognitive
4 decline with age. It's not meant to be a
5 double negative. It's really how the data
6 come out, is that individuals, their rate of
7 decline is less if they consume alcohol
8 moderately.

9 But again, there was insufficient
10 evidence to determine if drinking patterns
11 were important, although the caveat here is
12 there was a suggestion from a few studies that
13 heavy or binge drinking was detrimental to age
14 related cognitive decline. A few of these
15 studies, one in particular study from a
16 Scandinavian country really showed very strong
17 positive associations between heavy and binge
18 drinking and adverse cognitive function with
19 age.

20 So, you know, we have talked
21 during the last two days sort of about piling
22 on what was there already in 2005 as opposed

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1 to looking for new questions and asking new
2 questions that needed to be asked. The case
3 for heart disease and stroke is one of those
4 where I don't think it needs to be piled on.
5 There is a tremendous number of studies, great
6 scientific evidence before 2005 that already
7 pointed to sort of benefits of moderate
8 alcohol consumption for cardiovascular
9 disease.

10 The reason that we wanted to reask
11 this question, and again, maybe we'll keep
12 this, maybe we won't, is that we wanted to get
13 to drinking patterns. So the question we
14 asked is what is the relationship between
15 patterns of alcohol intake and cardiovascular
16 disease.

17 And this is one of the cases where
18 most of the inverse association between
19 alcohol and heart disease is pretty linear and
20 it continues down pretty far to four or five
21 and even six drinks a day before it starts to
22 come back up and be adversely related to

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1 disease. So this is one of the cases where
2 even heavy, frequent drinkers have lower rates
3 of heart disease from atherosclerotic disease.
4 So this may be one that's a little bit more
5 challenging to look at for patterns of
6 consumption because there is clear benefit
7 even with heavy frequent consumption.

8 So we didn't go back and review
9 all of the prospective studies for heart
10 disease because that list is now over about
11 120 studies. Instead we pulled out some of
12 the meta-analyses to see if they really gave
13 us insights into patterns of consumption.

14 We did pull the stroke papers.
15 There are 15 prospective cohort studies and
16 one case control study. The evidence here,
17 again, focusing mostly on patterns, is Grade
18 2. We felt that the evidence from
19 observational prospective studies again
20 strongly suggests that compared to non-
21 drinkers, individuals who drink moderately
22 have lower risk of heart disease and modestly

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1 lower risk of stroke.

2 There was really still, I think,
3 insufficient evidence to determine if drinking
4 patterns were equally predictive of risk,
5 although there was a suggestion, again, that
6 heavy or binge drinking was detrimental
7 especially for stroke.

8 So I don't know if I've answered
9 my own question saying maybe there's
10 insufficient evidence to go to the pattern
11 that -- go to the format that NIAAA used to
12 define patterns, but there is some evidence to
13 suggest that there may be differences in
14 patterns of the consumption over just a flat
15 cutoff for one a day for women and two a day
16 for men.

17 So the reason that we sort of held
18 up on making a final decision about I think is
19 driven by a few of the questions we haven't
20 gotten to yet. That is ethanol and
21 unintentional injury and predictors of alcohol
22 related disorders.

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1 Those two -- actually ethanol and
2 fractures also would probably be in that
3 range. If it turns out that we make a
4 recommendation that it's okay for women to
5 have three drinks on any given day and four
6 for men, yet we find in the literature that,
7 there's a tremendous amount of fractures and
8 unintentional injury associated with that,
9 then, of course, we would not want that to be
10 part of the recommendation.

11 So, you know, this is meant to be
12 a preliminary discussion of our findings. So
13 we may be more preliminary than most of you,
14 but I think it's driven by the fact that our
15 searches for unintentional injury, fractures
16 and alcohol related disorders may drive our
17 overall conclusions.

18 So that's where we stand, and I'd
19 be happy to take questions.

20 MEMBER PEREZ-ESCAMILLA: This is
21 Rafael.

22 Why cancer is not in the list?

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1 MEMBER RIMM: Thank you.

2 Sorry. I have written down here
3 cancer. Yeah, again, I think that there are a
4 number of things that are addressed in the
5 2005 dietary guidelines that we're not going
6 to pile on. Yes, we're going to discuss at
7 length the cancer issue. There was a WCRF
8 report that came out in 2007 which very nicely
9 documents the positive association between
10 alcohol and breast cancer. We didn't figure
11 that it was worthwhile to go back and review
12 papers in the last two years because there's
13 really, I think, almost unanimous evidence
14 that there's a positive association there, and
15 I think also for colon cancer there's some
16 evidence suggesting that alcohol increases
17 risk of colon cancer.

18 So those will be addressed, I
19 guess, in what we would call an exploratory
20 search and discussion which essentially points
21 out the other fantastic reviews that have been
22 done in the past that document that positive

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1 association.

2 MEMBER PEREZ-ESCAMILLA: And I
3 guess then the question is how will you make a
4 decision as to what to recommend.

5 MEMBER RIMM: Yes, right. So in
6 our brief subcommittee discussions the other
7 day, in the spirit of what we're trying to do
8 is reduce the number of questions. We
9 actually may reduce by getting rid of the
10 blood pressure question because it has been
11 addressed and it's likely not going to change
12 our overall guidelines, and we're probably
13 going to get rid of the mortality question
14 also because, again, there's been 140 papers
15 on outcome and mortality. Papers in the last
16 five years probably haven't changed our
17 thinking on that.

18 I think what I'll do is highlight
19 some of the key papers in the last five years
20 that have talked about ethanol mortality and
21 just point out that there seems to be, again,
22 continuing evidence to suggest that those

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1 women that average one drink a day live the
2 longest and those men that average two drinks
3 a day live the longest. So I think that's
4 where the balance will come, and there will
5 have to be a discussion of the fact that, you
6 know, ten times more women die of heart
7 disease than breast cancer, which is probably
8 why that J goes down to one for women, and the
9 same holds for men, is that there's more men
10 that die of heart disease and stroke than die
11 of colon cancer. So that's why the nadir of
12 that curve is probably at the average of two
13 drinks a day for men.

14 So clearly it's a balance. We're
15 not telling everybody to drink, but we're
16 trying to somehow balance these concerns with
17 some of the beneficial effects I talked about.

18 MEMBER ACHTERBERG: If I could
19 jump in, Cheryl here.

20 Call me thick, but are ethanol and
21 unintentional injury code for car accident?

22 MEMBER RIMM: This is Eric again.

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1 Sorry. I will not go on record by
2 calling you thick since I've been very
3 impressed with some of the presentations you
4 made today, but yes. The unintentional injury
5 is anything. Yeah, I mean, I think we're
6 talking about everything from -- you know, our
7 search will be broad, and that will include
8 car accidents. It will include, you know,
9 fights. It will include other social factors
10 that turn up when people drink in excess or
11 even drink at all.

12 So I think we're going to cast a
13 broad net to make sure that we're not
14 overstepping our guidance.

15 MEMBER ACHTERBERG: Okay, and now
16 I have a question. There are certain segments
17 of our population that do engage in binge
18 drinking heavily, and so one question is: are
19 there data out there now where we could look
20 at weight gain in, let's say, the college
21 student population who are binge drinkers
22 versus non-binge drinkers?

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1 MEMBER RIMM: You know, I think --
2 this is Eric again -- that's a challenging
3 question. There's a lot of data on binge
4 drinking in college students, and even some
5 data on college students that drink that don't
6 binge drink. You know, I think most college
7 students don't binge drink.

8 But I think the issues will be I
9 have not seen great prospective, long-term
10 studies that have tried to document the fact
11 that it's the beer over the pizza over the
12 lack of exercise, over the other factors that
13 contribute to weight gain in what we would
14 classically -- you know, the first two years
15 of college.

16 So I have not seen evidence,
17 although I haven't explored that in detail,
18 but when we look at alcohol and weight gain,
19 there was nothing that came out specifically
20 on college drinking that's binge drinking.

21 MEMBER ACHTERBERG: Thank you.

22 I'm also, frankly, thinking of an

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1 adolescent population, and we probably have
2 less data on that, but we know a lot of
3 adolescents also binge drink, and we shouldn't
4 forget that. I don't know what to look for
5 there. It might be implications. It might be
6 future research, but somehow we have to
7 comment on that.

8 But if there is any relation at
9 least in that population segment relating
10 alcohol intake to weight gain, that might be
11 some of the best leverage we have to
12 discourage people at least in that age range
13 from binge drinking.

14 MEMBER WILLIAMS: This is
15 Christine Williams.

16 Along that line, I think one of
17 the public comments had to do with
18 discouraging under age drinking based on the
19 direct damage to the brain. Did you consider
20 looking at that evidence?

21 MEMBER RIMM: I think that did
22 come up briefly in one discussion, and we sort

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1 of felt like that was almost beyond our
2 purview and expertise to start talking about
3 things which already are illegal and should be
4 avoided.

5 So I mean, I guess, is that
6 related to purpose of the dietary guidelines,
7 to start giving, you know, the advice that
8 it's not like we're telling people to have
9 seven grams of sodium and it's going to cause
10 brain damage.

11 So I guess that's something we can
12 talk about. It's a discussion, you know.
13 Should we go there? Should we start talking
14 about adverse effects for something which, you
15 know, regardless of the fact it may be
16 dangerous to the brain, you know, it's flat
17 out illegal?

18 So if we're going to use the
19 dietary guidelines as something that, again,
20 as you say, leveraged to try to get
21 individuals to stop drinking, then maybe we
22 could explore that in more detail. I don't

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1 know if we have the expertise in the panel,
2 but we could seek that expertise if it's
3 really something that the committee thinks is
4 worthwhile.

5 MEMBER PEARSON: Eric, this is Tom
6 Pearson.

7 We had talked about this in the
8 subcommittee, but one of the obfuscating parts
9 of the discussion on cognitive function or
10 dementia is I think if you look at it
11 hematologically, those things that prevent
12 stroke prevent cognitive decline and dementia
13 because of the mixing of those disorders, and
14 so that certainly part of the people we might
15 call Alzheimer's without benefit of further
16 testing or other kinds of things probably are
17 multi-infarct dementia, a subset of stroke.

18 So I wonder. Maybe it's a
19 research recommendation, et cetera, but it
20 would be awfully nice if you got into
21 something like mace or something in which you
22 could sort those out and which really identify

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1 a subgroup of individuals without any evidence
2 of cerebral vascular disease and really ask
3 whether, you know, the neuronal effects of
4 moderate to high alcohol or even binge use of
5 alcohol was, in fact, affecting them, and I
6 think right now I certainly would have a hard
7 time saying if, in fact, you found some
8 beneficial effects on cognitive function or
9 reduced dementia, that that wasn't just
10 another chapter on the stroke story.

11 MEMBER RIMM: This is Eric.

12 Yeah, I think that's clearly one
13 of the biological hypotheses put forward for
14 why there is a decrease in the rate of
15 cognitive decline. So, yeah, it may just be a
16 statement to that.

17 I think there have been a few
18 other hypotheses put forward, but I think
19 that's clearly the strongest one.

20 I should point out that in the
21 NIAAA document where they're talking about
22 sort of the differences for men and women, at

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1 the bottom they do sort of say or they do
2 specifically say for individuals 65 and over,
3 the recommendation is the same as the
4 recommendation for women, regardless of your
5 gender. So that if you're 65 and older, it
6 should not be more than three drinks in any
7 setting, and whatnot, not more than seven in a
8 week.

9 So it does speak to the fact that
10 there are differences in metabolism over age,
11 and there may be, you know, more risk for the
12 adverse effects of a spike in blood pressure
13 or a spike in something else that comes with
14 heavier alcohol consumption.

15 JOANNE SLAVIN: I want to talk
16 just a little bit about nutrient adequacy.
17 Does that get pulled in here as people drink
18 and dilution of the -- it relates to the
19 nutrient adequacies, three drinks a day, four
20 drinks a day. When you look at those numbers,
21 half of the people's calories are going to be
22 alcohol. So it is going to affect nutrient

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1 needs for sure.

2 MEMBER ACHTERBERG: Discretionary
3 calories.

4 MEMBER RIMM: Yes, I mean, that's
5 clearly what it is. To use the verbiage in
6 2005, it's discretionary calories. So do we
7 need nutrient adequacy on every single day?
8 That's the question. Are we talking about
9 weekly averages or are we talking about a
10 longer period of time?

11 I think that's why the NIAAA sort
12 of caged that in the case of weekly, not
13 because we realize in any given day people may
14 differ. They may have a lot more dark green
15 leafy vegetables on one day and a lot more
16 carrots and tomatoes the next day that will
17 provide different nutrients, but on average
18 over the course of the week, they're going to
19 have the right amount of servings of fruits
20 and vegetables.

21 So if someone has four drinks on
22 Tuesday and three on Wednesday and four on

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1 Thursday, you're right. That's a fair bit of
2 calories that are displaced. I'm hoping that
3 that's in excess of their discretionary
4 calories for those days. I would hope they
5 would make it up during the rest of the week.

6 And right now it looks like in
7 free living populations individuals who drink
8 on average one to two drinks a day don't gain
9 weight. Now, I don't think it's magic. It's
10 not like the calories disappear. So there is
11 clearly some individuals who have the ability
12 to themselves take out calories when they're,
13 you know, drinking alcohol.

14 Now, there are some metabolic
15 effects that may actually increase your basal
16 metabolic rate for the short amount of time
17 that you're metabolizing ethanol, but I think
18 for the most part people are just displacing
19 themselves.

20 CHAIRPERSON VAN HORN: Yet I think
21 one of the things going back to the
22 discretionary calorie issue is unfortunately

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1 the behavior of drinking is often associated
2 with a loss of inhibition, and so you
3 basically wind up consuming more calories at
4 the time than you normally would.

5 So I do think that just as we know
6 that overweight people under report calories
7 and over report physical activity, we also
8 know that people who drink more report less in
9 terms of their alcohol consumption as well.

10 And so, again, with our focus
11 constantly on the obesity epidemic, I don't
12 think any of us would suggest that for someone
13 who is overweight one of the things we would
14 recommend in terms of helping them lose weight
15 and control their weight gain would be to
16 limit their discretionary calories and to
17 point out that if you're consuming 300, 450
18 calories and that's three drinks in one day,
19 that totally eliminates any other options as
20 far as other discretionary choices.

21 So I think, you know, as we were
22 saying earlier about liquid calories versus

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1 solid calories, I think it sort of enters into
2 this discussion as well. People don't
3 necessarily perceive that drinking that glass
4 of wine is equivalent to, you know, a brownie
5 in terms of the calories.

6 MEMBER RIMM: Thank you, Linda.
7 This is Eric.

8 And I think you brought up several
9 good points. I think a brownie is probably
10 more than 100 calories, first of all. No, I
11 think the first point you brought up about,
12 you know, people who are overweight obviously
13 are not going to use alcohol to lose weight.
14 There's no evidence, there's no study that has
15 ever shown that. The randomized trial here
16 was not using alcohol. They were both diets.
17 Both arms were on an energy restricted diet.
18 So it was just that -- anyway, you get the
19 point.

20 So I hope I didn't get that point
21 across. So I think you're clearly right, and
22 I think that if you are overweight that, you

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1 know, individuals do look to discretionary
2 calories to reduce their caloric consumption,
3 and I think that's one of the reasons why we
4 didn't include cross-sectional studies in any
5 of our analyses, and I think that maybe all of
6 us should look to that because cross-sectional
7 studies of diet are always fraught with the
8 fact that as people are overweight, they look
9 to discretionary calories or look to changes
10 in their diet. So it ends up looking like
11 diet Coke causes obesity because people are
12 overweight and drinking diet Coke.

13 Alcohol may be the same way, which
14 I think is, you know, something we have to
15 really carefully take into consideration.

16 But to your other point, you know,
17 people who drink may lose, you know,
18 inhibitions and then eat more. I think that's
19 why we see in almost all of the prospective
20 studies that have enough power that people who
21 average more than two drinks a day on average
22 gain weight.

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1 So clearly there is something to
2 it. It's not disappearing and maybe they're
3 eating more peanuts when they're drinking. So,
4 you know, I think there's a lot of things that
5 go on when we talk about the health effects of
6 alcohol. So it is a challenging thing, and
7 that's why we're sort of grappling with the
8 fact of how do we deal with patterns.

9 Because we want to capture, you
10 know, how people drink. I think it's really
11 kind of naive to think that everybody drinks
12 on average one drink a day for women and two
13 drinks a day for men. There is not that many
14 people that drink every day.

15 So the issue is can we capture
16 that in the guideline and can we give people
17 the correct advice as opposed to being just
18 restrictive saying, "Never drink more than two
19 for men and never more than one for women."

20 CHAIRPERSON VAN HORN: Well, and,
21 again, just to zero in on this topic because
22 we know the majority of our population is

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1 overweight or obese, so everything that we're
2 recommending in these guidelines will address
3 a population that is overweight or obese.

4 And so we can't ignore the fact
5 that for the majority the question of
6 discretionary calories from alcohol is an
7 issue, and they need to understand that if
8 you're going to drink, if that's your choice,
9 you have no other options as far as other
10 foods, fun foods, whatever we want to call
11 them, because you've already blown your wad,
12 so to speak, in regard to the alcohol that
13 you've consumed.

14 That's the message that I think
15 will be a little challenging to get across but
16 needs to get across because our population is
17 overweight already.

18 MEMBER RIMM: Yes. Those are good
19 points. I mean, everything that we've talked
20 about in the last few days, it's always hard.
21 Once you put a number up on the screen people
22 look to that as a target. I don't think we're

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1 using as a target that every man should drink
2 14 drinks in a week and every woman should
3 have seven drinks in a week.

4 I don't think I would want to
5 scare people away from drinking alcohol
6 because there are clearly health benefits. An
7 individual who is overweight, there's very
8 clear evidence that an individual who is
9 overweight who drinks alcohol has about a 40
10 percent lower risk of developing diabetes than
11 someone who doesn't drink. It clearly
12 increases insulin sensitivity. There are
13 clear biological effects.

14 Now, I'm not going to prescribe
15 that overweight people drink alcohol because
16 there's lots of other things they can do, but
17 I would be concerned about a guideline coming
18 out saying if you are overweight you should
19 stop drinking because I think that could be
20 more detrimental than helpful.

21 So it's clearly a balance and, you
22 know, a lot of the things we've talked about

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1 are balances, and Rafael's issue of dietary
2 patterns is a balance. You know, the issues
3 of sodium are a balance. I think this is one
4 of those things where there has to be a
5 balance. It's just that unfortunately on the
6 high end of this balance scale there's a lot
7 of really bad health outcomes. So we have to
8 take that into consideration.

9 MEMBER PEREZ-ESCAMILLA: Eric, I
10 believe in the previous guidelines one
11 recommendation was if you are not a drinker,
12 don't start drinking now to get this benefit.
13 Would that remain your position?

14 MEMBER RIMM: Yeah, I mean, that
15 has been the underlying -- the first sentence
16 of every guideline since 1980 when alcohol was
17 included when the first dietary guidelines
18 came out. That is the guideline for any
19 agency that put something out, saying if you
20 don't drink, don't use this as a reason to
21 start and don't start.

22 I mean, I showed you 25 percent of

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1 men and 35 percent of women don't drink. They
2 don't drink for a reason. It's not that
3 they've never seen alcohol. You know, it's
4 religious reasons. It's for health reasons.
5 It's for, you know, they drive and they drop
6 (phonetic). So this clearly will not change.
7 That's a very important point.

8 As well, the point, actually one
9 thing I didn't talk about. The points about,
10 you know, drinking if you are pregnant,
11 drinking if you're driving, all of those
12 things obviously still hold, and if anything
13 there's now even stronger evidence.

14 So the one thing where there is
15 challenge and the one thing I didn't address
16 yet which will be something for us to discuss,
17 that again I would like maybe Christine's
18 input and others, is that the last question on
19 ethanol and breast feeding, and this has been
20 a question where it hasn't really been
21 addressed or if it hasn't been addressed, it's
22 been if you are breast feeding, don't drink,

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1 and we really wanted to try to see what the
2 literature was. Is there really evidence to
3 support that?

4 Everybody is concerned about the
5 infant getting ethanol through the breast
6 milk, and we know ethanol exists there, and we
7 do know that there's a modest reduction in
8 breast milk if you are drinking. So the
9 question really is to us if someone looks at
10 the guidelines as, you know, if I'm breast
11 feeding I shouldn't drink. Therefore, I'm
12 going to stop breast feeding.

13 You know, there is evidence to
14 suggest that in all sorts of different
15 cultures, that they want to have a drink once
16 in a while, not drinking in excess; want to
17 have a drink once in a while. So they give up
18 breast feeding.

19 Now there is actually one paper
20 that NEL identified a few weeks ago which is a
21 very nice paper, sort of looking at a woman's
22 weight and how much they're drinking and how

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1 long the ethanol stays in the breast milk such
2 that, again, it's more of a timing issue; that
3 if you want to breast feed and you also want
4 to have a glass of wine once in a while, that
5 if you time it, that it really only takes two
6 to three hours for the ethanol to get out of
7 the breast milk; that you can still have your
8 three drinks a week and still continue to
9 breast feed.

10 So that's one of the challenging
11 questions that we hope to address at the
12 subcommittee.

13 MEMBER PEARSON: Eric, this is Tom
14 Pearson.

15 Is this NIAAA publication on the
16 Website?

17 MEMBER RIMM: Yes.

18 MS. McMURRY: Yes, it is. Kathryn.

19 MEMBER PEARSON: I guess the
20 question I had is it would be interesting to
21 look at their grade of evidence according to
22 our criteria for their recommendation because

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1 I think what you've said is that for up to
2 four drinks you're having a very hard time
3 finding risk or benefit from that either.

4 I guess maybe where I'm going with
5 this is that this recommendation is really to
6 assuage people from alcohol abuse, I think.

7 MEMBER RIMM: Yeah, I mean, and I
8 --

9 MEMBER PEARSON: And maybe our
10 goals are different. That is, I guess, my
11 point.

12 MEMBER RIMM: No, that's a good
13 point. I think NIAAA does not have this same
14 foundation of standards saying you have to go
15 to the evidence library and you have to share
16 with all of the available evidence that this
17 is the case.

18 So I guess, you know, they have
19 summarized the literature and they have their
20 own studies, and it suggests that people who
21 drink like that don't have -- you know, are
22 low risk drinkers, that they would qualify as

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1 low risk drinkers.

2 So with their being a little bit
3 more flexible saying, you know what? It's
4 okay to drink like this. You know, don't
5 worry about your consumption if you're up to
6 four drinks in a day just as long as you don't
7 drink more than 14 a week.

8 And I don't see any evidence to
9 say that that's wrong. I don't see any
10 evidence necessarily to say it's really, you
11 know, incredibly right and it's just exactly
12 the same as the previous evidence, but there's
13 not evidence to say that it's wrong, you know,
14 four drinks a day for men on any given day is
15 going to necessarily impact their rates of
16 heart disease, stroke, breast cancer or color
17 cancer any differently.

18 But I will say we haven't
19 necessarily looked at all of the evidence for
20 unintentional injuries and fractures where I
21 will probably see where it's probably two to
22 three or four times increased risk.

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1 MS. McMURRY: Kathryn McMurry,
2 HHS.

3 I just wanted to try to clarify
4 the dietary guidelines' recommendations for
5 moderate alcohol consumption. Historically it
6 has been a daily limit, not an average weekly
7 limit, and the 2005 dietary guidelines
8 committee report on page 218 says a daily
9 intake of one to two alcoholic beverages is
10 associated with the lowest all cause mortality
11 and a low risk of CHD among middle aged and
12 older adults.

13 And it goes on to say if alcohol
14 is consumed, it should be consumed in
15 moderation and only by adults. Moderation is
16 defined as consumption of up to one drink per
17 day for women and up to two drinks per day for
18 men, although the committee did look at
19 research among people who consumed four or
20 fewer alcoholic beverages per day, and that
21 might be the source of some of the unclarity.

22 MEMBER RIMM: Well, I think the

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1 issue is that all of the papers that are
2 summarized in the 2005 dietary guideline
3 report are all based on average consumption.
4 They're not one drink a day, up to one drink a
5 day for women, up to two drinks a day for men
6 because those data for the most part didn't
7 exist. It has only been in the last eight to
8 -- yeah, five to eight years that there's been
9 a lot more data on dietary patterns or on
10 alcohol patterns where they actually looked at
11 days per week and how many alcohol drinks were
12 consumed on those days.

13 So that's why I said it was sort
14 of implied, but in the end they did say one
15 drink a day for women and two drinks a day for
16 men, but I think implied in that was that it
17 was average consumption because they were
18 basing it on data that was all average
19 consumption.

20 MEMBER PEARSON: This is Tom
21 Pearson.

22 But underlying this is an

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1 individual using alcohol as a beverage or a
2 drug, and I think the pattern of a drink or
3 two a day, I think you could suggest might be
4 associated with a lot of other healthy
5 lifestyles. I mean, it's just a moderation
6 thing kind of versus -- again, this is one of
7 those average versus this maximum. You know,
8 I'd certainly be more comfortable with the two
9 being a maximum rather than this four and none
10 in which you might have an individual who's
11 using this not as part of a healthy diet but
12 rather as something else.

13 MEMBER RIMM: Yeah. I mean, I
14 think that the reason that I brought up this
15 NIAAA document, one is it just came out, is
16 useful to talk about and publicize. The
17 second thing is that we're going to have the
18 case where there's going to be two different
19 government agencies that have essentially two
20 different guidelines.

21 That's not to say that government
22 agencies always all agree on everything and

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1 the guidelines are always going to be the
2 same, and they clearly didn't have the same
3 sort of requirements for evidence base on the
4 world's literature as we may have. So I
5 wanted to at least look at it and address it
6 to see, you know, is this an acceptable
7 guideline. Should we go with something that
8 would be consistent that would then become
9 more of a uniform guideline or if the evidence
10 doesn't support it, of course, we would go
11 back to something which is best supported by
12 the evidence.

13 So I'm not tied to it. I'm just
14 saying that we're putting it out there and I'm
15 not going to encourage all college students
16 around the country to write letters to me like
17 you did, but I clearly would love to hear
18 people's opinion on this.

19 MEMBER APPEL: Yeah, Larry Appel.

20 Eric, I have a question about the
21 NIAAA. Is this really sort of a guideline
22 that's based on the evidence or was it deemed

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1 sort of like a more practical type of
2 recommendation because the evidence actually
3 becomes a circular argument, you know, the way
4 they've defined it. The problem drinker is a
5 non-binge, you know. It's a bit circular.

6 So it's easy to say that this is
7 consistent with a low risk population because
8 a high risk person almost by definition is
9 over 14 per day or is drinking five or more,
10 you know, on an occasion.

11 But it seems to me that it might
12 have been just sort of a way to say, okay,
13 well, we know that when a woman drinks it's
14 very unlikely it's just one a day, you know.
15 They probably are drinking maybe two or
16 something like this and men maybe not two or
17 three.

18 So do you know if this is really
19 based on some sort of, you know, real evidence
20 or is it just sort of this makes more sense?
21 The reason I bring that up is because that
22 would be a potential translation improvement

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1 if they thought that this was just a more
2 practical guideline than what has been out
3 there before.

4 MEMBER RIMM: yeah, I mean we can
5 go back and ask someone at NIAAA for insights
6 into this. Again, what I have is what I've
7 seen, and for the most part I realize that
8 this is something really not geared at
9 defining, hey, this is the way everybody
10 should be drinking. This document is geared
11 at trying to help people who drink in excess
12 of that.

13 So it gives people ideas, gives
14 people suggestions, gives ways to identify the
15 fact that if you are not a low risk drinker
16 how can you get to that? So I think it really
17 is a practical way of getting people down from
18 drinking in excess of that, of 14 and seven.

19 Now, obviously why we're arguing
20 this back and forth is because this is saying
21 you can drink up to four for men and up to
22 three for women, and I think that also may be

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1 just a practical way to start from drinking in
2 excess of that to get to that level to feel
3 like you've made some progress and that you
4 are now drinking at a level which is of lower
5 risk.

6 Now, again, I think they're basing
7 this mostly on their own NIAAA studies, and I
8 don't think it's meant in the same way. I
9 really don't think it's meant as this is an
10 alcohol guideline that everybody should be
11 following. I think it's meant to be in a
12 pamphlet to help drinkers -- people who drink
13 in excess to drink less.

14 But I think it's a good idea. It's
15 funny that I'm getting 80 percent of the
16 questions from people in my own subcommittee.

17 (Laughter.)

18 MEMBER RIMM: Rachel, this is a
19 sign to us we need to meet more frequently.

20 (Laughter.)

21 MEMBER RIMM: But I think we
22 should welcome someone from NIAAA to give us a

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1 much more detailed description of what led to
2 this. How did you go about doing it? And you
3 know, I would welcome the discussion, and I
4 think maybe this is an implication that we
5 have in the dietary guideline where we point
6 to this saying here's one way if you drink in
7 excess -- here's a great way to get to a lower
8 level.

9 MEMBER APPEL: Yes. I think the
10 other thing, they sort of crosses my mind, and
11 I'm sure you, too. It's like any time you
12 sort of like make a change in a number, I
13 mean, that becomes a headline, and it's a
14 headline that it's going to be misinterpreted,
15 too. So maybe they've even done some, you
16 know, qualitative research in the public that
17 this did or did not seem to have an impact on
18 how people drink.

19 If we were to make a change or
20 accept this, you know, that would probably get
21 a lot of attention, and we would probably be
22 wondering ourselves, you know, are we creating

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1 more harm by giving potential license going
2 from what is under two to up to four and would
3 the people, you know, go further.

4 MEMBER RIMM: Yeah, you're right.
5 I think looking at some of Patricia's data
6 that she did for us, I mean, there's a lot of
7 people who are drinking outside of the dietary
8 guidelines. So I'm not trying to sort of
9 massage the dietary guidelines so that it
10 looks like we don't have as much drinking
11 problems in this country.

12 So I agree. I mean, this should
13 not be in the top five things that get
14 screamed from the rooftops when the dietary
15 guidelines come out. I really think that
16 sodium in children, you know, and things
17 related to body weight control should be
18 screamed from the rooftops. This should be
19 something that, you know, is driven by the
20 evidence.

21 DR. POST: Yeah, hi. This is Rob
22 Post.

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1 I've got a question, and that is
2 if you're going to consider calories declared
3 on labeling when we're talking about
4 discretionary calories, I know that's an issue
5 that may have been brought up in comments
6 received, but it looks at it from a more
7 practical standpoint.

8 MEMBER RIMM: Yeah, I mean, that
9 is a challenge, and I know it has been
10 something that's been debated for a fair bit
11 of time, and I'm all for sort of freedom of
12 information. I really think that when people
13 make choices they should know what they're
14 consuming. They should know how much calories
15 are in what they're choosing.

16 So I am strongly in favor of that.
17 Again, I'm not familiar with the evidence that
18 there's been enough studies saying that people
19 altered alcohol consumption based on if they
20 saw a label or not that had caloric content,
21 but you know, I think that body weight is the
22 theme of this dietary guidelines, and if

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1 drinking in more than two drinks a day leads
2 to weight gain and if labeling the beverage
3 helps with that, then I would be all for it,
4 and I think maybe that could be one additional
5 piece that would help to guide that.

6 You know, I am all for information
7 and having the information on the alcohol
8 package also is very important.

9 CHAIRPERSON VAN HORN: And that
10 really is a cross-cutting theme, I think, of
11 this group, you know, that providing that
12 information and raising to the attention of
13 the public the caloric content of food so
14 that, indeed, informed choices can be made in
15 light of the need to pay attention to weight
16 control, you know, is something that cuts
17 across every single subcommittee that we've
18 discussed. So I think that's another aspect
19 of this.

20 I think we're at the point now
21 where we can actually open the floor to
22 discussion on any of the topics that we've

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1 discussed over these last two days. I want to
2 just congratulate everybody because I think
3 the amount of effort that has been put forth
4 is just really unbelievable, to use a word I
5 just heard.

6 And I think that we, indeed, have
7 recognized, you know, that this is a very
8 ambitious group, and if anybody can do it, I
9 think this group can do it, but I also think
10 we are now recognizing on the basis of the
11 effort that has been put forth for this
12 meeting that we have perhaps more than our
13 fair share of work cut out for us.

14 And so our goals now, I think, are
15 as subcommittees to go back and reconsider and
16 reprioritize the key questions and topics that
17 we think really need to be addressed, but now
18 is the chance. I would like to open it up.

19 Are there things that any of the
20 committee members would like to raise for
21 discussion? Larry, you look like you do.

22 MEMBER APPEL: Larry Appel.

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1 In the context of sort of
2 trimming, I think one of the things that we've
3 done on our subcommittee that might be another
4 reason to trim is that we've dealt with a lot
5 of sort of contextual issues. So if all of
6 the committees are doing is just, you know,
7 going through the process and counting up
8 positive and negative studies and not dealing
9 with, you know, some of the important, you
10 know, I'll call them -- I don't know --
11 contextual ancillary issues which actually
12 deserve a lot of discussion, you know, like we
13 said the enhanced meat issue and other things
14 that might be just as similarly important on
15 their committees.

16 So it's another reason to start
17 trimming the sails.

18 MEMBER RIMM: This is Eric Rimm.

19 I think related to that, you know,
20 I think I would urge all subcommittees to take
21 into consideration that this is more than a
22 bean counting exercise. I've come up myself

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1 in just looking at my own studies for some of
2 the questions that I've had, and it's really
3 hard. It takes a lot of time to look at every
4 study, but I think we can't equate. All
5 studies are not the same, and there is a time
6 -- and I don't think all prospective studies
7 are the same, and I don't think all randomized
8 clinical trials are the same.

9 And so I know why the quality of
10 the study is rated as positive, neutral or
11 negative quality, but sometimes I don't know
12 if that's enough or depending on the context
13 of it if the way those quality scores are set
14 up are correct, but I think we could get a lot
15 more out of it if instead of counting 20
16 studies we actually looked at the four best
17 studies.

18 And I think the reason that we're
19 around this table is because we're experts in
20 an area. So I think at some point there has
21 to be a decision made where, you know, it
22 turns out there's 20 studies, 16 of them that

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1 were poorly done and, you know, barely
2 published, found one thing, and then the four
3 that were excellent found the other thing. I
4 think we have to put weight on the four
5 studies even though the study designs may be
6 one way or the other.

7 I realize I have some of those bad
8 papers that you're citing, and so I don't mind
9 my own papers being personally discounted if
10 they don't hold up to some of the other
11 papers. So I really think that it's time when
12 we get down to the final questions that we
13 really do look at the study quality.

14 CHAIRPERSON VAN HORN: I would
15 like to echo that. You know, it's interesting
16 that we're at a point of evidence based
17 reports suggesting that we no longer need the
18 expertise, in fact, and all we do is bean
19 count and decide how many are on this side
20 versus that side, and clearly that's not at
21 all what needs to be done.

22 If anything, now more than ever

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1 the kind of judgment that you're suggesting is
2 required because you have to know something
3 about science and research and understand the
4 topic and what are those nuances.

5 In my case, for example, what was
6 the diet assessment method used and can you
7 really rely on those data on the basis of the
8 way those diet data were collected, and
9 sometimes the answer is yes and sometimes it's
10 no.

11 So I think that in every one of
12 our subcommittees, you know, there are those
13 kinds of questions that have to be weighed and
14 balanced and evaluated because we actually do
15 make decisions.

16 I also think just for the purpose
17 of those listening that this group has said
18 over and over again that ultimately if no data
19 exists or inaccurate or questionable data
20 exists, there is a certain amount of
21 responsibility felt by this group to come up
22 with the best judgment in terms of how to

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1 treat that.

2 And I think that, again, that's
3 the beauty of having a group like this
4 convened with interdisciplinary expertise and
5 the ability to really wade through all of this
6 and come up with something reasonable as far
7 as what to recommend.

8 So I think at this point, other
9 topics on any other questions that have been
10 addressed? Everyone is looking a little
11 exhausted at the moment.

12 Yes, go ahead, Tom.

13 MEMBER PEARSON: Well, this
14 caloric adjustment question came up and that
15 was one of the things that I think we haven't
16 resolved in terms of expressing nutrients on
17 the basis of calories versus milligram
18 amounts. It's fiber; it's sodium; it's fat;
19 it's cholesterol.

20 CHAIRPERSON VAN HORN: Right,
21 right. I think --

22 MEMBER PEARSON: It would be nice

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1 if we did something standardly.

2 CHAIRPERSON VAN HORN: Right. If
3 we think that it is applicable in a standard
4 way. I know in the sodium -- and, Larry, you
5 can speak to this -- but in the sodium
6 discussion it was decided that calorie
7 adjustment for that would not be a benefit
8 because of some of the things Christine said,
9 and you know, in terms of children as well as
10 just realizing there's an absolute amount here
11 that does make a difference in terms of blood
12 pressure and other issues.

13 But you know, to do that in each
14 of the subcommittees related to their issue,
15 whether it be fiber or cholesterol or what
16 have you, I think that requires a little more
17 contemplating.

18 Larry.

19 MEMBER APPEL: Yeah, Larry Appel
20 again.

21 I think just a little bit of a
22 refinement. What we decided in our

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1 subcommittee, and maybe we need to just make
2 sure, is that we're not going to adjust the
3 recommendation based on calorie intake. On
4 the other hand, there's a charge to Trish and
5 also subcommittees to think about whether the
6 tables for, you know, the dietary patterns
7 could be adjusted just because there is the
8 practical aspect to this.

9 Now, you know, I'm not quite sure.
10 There's a bit of a disconnect, but there is
11 also the reality, you know, that people who
12 eat together have very different calorie
13 intakes and they're not preparing different
14 meals for people with higher calorie levels.

15 CHAIRPERSON VAN HORN: Right,
16 exactly. Other general topics? Shelly.

17 MEMBER NICKOLS-RICHARDSON: This
18 is Shelly. I just wanted to go back to the
19 cholesterol question, the 300/200 level. In
20 looking at the modeling that Trish has already
21 done with the ideal representative foods, when
22 you get below 1,600 calories, you can then get

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1 below 200 milligrams of cholesterol in the
2 diet, but above the 1,600 calorie level, just
3 based on a little bit of what Trish has here,
4 it's very difficult to get below the 200
5 milligrams.

6 So we already have some of that
7 modeled.

8 CHAIRPERSON VAN HORN: Okay. Well,
9 with that, just a few closing comments, and
10 we'd also like to hear from Raj.

11 And I'd just like to briefly
12 review the next steps for our work. Between
13 now and the fifth meeting each subcommittee
14 will finish drafting its proposed conclusion
15 statements for all of the remaining research
16 questions, realizing that some of those may
17 get triaged.

18 The subcommittee chairs will leave
19 the drafting of the content for their
20 respective chapters and work with the science
21 writer on organization and flow within their
22 chapters.

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1 At this fifth meeting that's
2 likely to take place in the first quarter of
3 2010, each subcommittee will present the
4 proposed conclusions for the remaining
5 research questions for the report. The focus
6 of this fifth meeting will be to come to
7 consensus on the science and consider the
8 integration of our conclusions into the food
9 based recommendations that will ultimately be
10 made.

11 And as I mentioned at the start of
12 the meeting yesterday, there will be a sixth
13 and final meeting after the report is complete
14 that will be held via Webinar for both the
15 committee members and the public, and at that
16 meeting we'll present and vote on the approval
17 of this report.

18 After that the report will undergo
19 final formatting and formal discussion to
20 submit the advisory report to the Secretaries
21 of USDA and HHS who will then post it for
22 public comment.

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1 And with that, I'd just like to
2 ask Raj to address the group.

3 DR. ANAND: Penny and I were
4 talking just two minutes ago that how exciting
5 it has been to be here. I'm really impressed
6 by the caliber of discussion and the caliber
7 of the committee members. I really want to
8 thank each one of you for really spending your
9 time and your energy on this one, and
10 especially to Linda Van Horn for chairing this
11 meeting.

12 Arranging a meeting takes a lot of
13 time, a lot of people. So if you will give me
14 the liberty to acknowledge some of the people
15 that have worked behind this one.

16 First of all I would like to thank
17 the people from HHS, Penny Slade-Sawyer and
18 Sarah Linde-Feucht. We thank you very much
19 for coming and participating in it.

20 Second, I would like to
21 acknowledge the role of three Executive
22 Secretaries: Carol Davis, Kathryn McMurry,

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1 and Shanty Bowman. Thank you for taking part.

2 We have several people. I'll just
3 name them from CNPP: Jan Adams, Trish
4 Britten, Eve Essery, Patricia Guenther, Kellie
5 O'Connell, Colette Rihane, Joanne Spahn, Joan
6 Lyon, Yat Ping Wong, Jean Altman, Donna Blum-
7 Kimelor, Eve Essery, Thomas Fungwe, Patricia
8 MacNeil, Molly McGrane, Julie Obbagy.

9 These people have really worked
10 very hard for over the past several days and
11 arranged this one.

12 Then we have people from HHS:
13 Holly McPeak, Shirley Blakely, Rachel Hayes.

14 And I also want to acknowledge the
15 ERS that have given us this facility, very
16 nice facilities, and the staff that really
17 helped the logistics were Dominique Harris,
18 Pat Cleveland, and LeShawn Williams.

19 We want to thank each one of you
20 for your work and your effort to make this
21 meeting a really enjoyable experience.

22 Thank you very much.

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1 CHAIRPERSON VAN HORN: Thank you
2 very much Raj, and I would just echo that to
3 all of the committee members and everyone
4 gathered here and Rob Post, just all of the
5 work that's going on. It's really impressive,
6 and it's really a privilege to be a part of
7 this illustrious group.

8 So thank you all so much and we'll
9 be back in February. Thank you.

10 (Whereupon, at 3:26 p.m., the
11 meeting in the above-entitled matter was
12 concluded.)

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