

1 information based on authoritative statements that mimic
2 those barriers deemed unconstitutional in Pearson versus
3 Shalala.

4 We will hope for the former and, as lawyers are
5 fond of saying, we will see you in court if the latter.
6 Thank you very much.

7 MR. LAKE: Thank you.

8 Our next speaker is Richard L. Hanneman, president
9 of the Salt Institute.

10 MR. HANNEMAN: Good afternoon. I'm going to
11 change directions from what you've had the last couple of
12 times.

13 I am Dick Hanneman. I'm the president of to Salt
14 Institute and we are the trade association of manufacturers
15 of sodium chloride, salt, which is the largest source of
16 dietary sodium, and we're here to talk about some lessons we
17 think from what we've done so far that may be useful for
18 FDAMA's implementation. Particularly my message is one of
19 consistency, the importance of consistency.

20 FDA faces difficult challenges in implementing
21 FDAMA, particularly in extending the basis for health claims
22 on food labels, and the challenge grows from the
23 inconsistency with which FDA has implemented NLEA from the
24 beginning, especially in its treatment of issues surrounding
25 the presence or absence of significant scientific agreement,

1 as well as the difficulty in adjusting health claims to be
2 current, to reflect advancing science.

3 Therefore, even before considering the question of
4 what outside bodies, what authoritative sources might be, we
5 think that we ought to consider the sources of internal
6 consistency and see whether we can improve that.

7 I was struck by Dr. Lewis's framework discussion
8 this morning where she said that there would be some point
9 after the statement is determined to be authoritative where
10 the SSA would come into play.

11 Let me just share our example with you. There are
12 a couple in my written statement and there are citations for
13 what I've stated. The example I would raise with you today
14 is the science used to support the sodium and hypertension
15 health claim, which has been approved, and the fact that it
16 does not seem to be nearly as compelling to support that as
17 that which was offered to support a health claim for calcium
18 hypertension, which health claim was denied.

19 For example, FDA has maintained the health claim
20 for sodium, despite the fact that serious scholars are in
21 widespread disagreement about the meaning of the science,
22 that expert societies continue to debate it. FASA just a
23 couple of weeks ago, the American Society of Hypertension
24 next week, that NHLBI has just in January of this year
25 conducted a workshop at which the experts were convened and

1 reached absolutely no consensus. And the world's premier
2 general science journal Science has documented efforts by
3 NHLBI to make sure that the end result of our reading of the
4 science is consistent with their policy, quite a tortured
5 effort.

6 FDA maintains a sodium and hypertension health
7 claim, although the scientific rationale is limited and
8 questionable. The meta-analyses of the clinical trials find
9 a small overall population blood pressure reduction on low
10 sodium diets, but the benefit being confined to a subset of
11 older primarily and salt-sensitive individuals with
12 hypertension.

13 There have been six studies that have examined the
14 fundamental question of whether low sodium diets reduce the
15 risk of cardiovascular events and all of them were either
16 totally inconclusive or disturbingly adverse to FDA's
17 interpretation of the science and its health claim.

18 And the NHLBI-funded trials of hypertensin
19 prevention phase 2 documented no significant diastolic blood
20 pressure reduction, which was the primary hypothesis, and a
21 reduction from 127.7 millimeters mercury to 127.1
22 millimeters of mercury the secondary hypothesis.

23 Against that backdrop then, let's consider what
24 evidence FDA determined to be unpersuasive when it denied
25 the petition for a health claim for calcium and

1 hypertension. Our reading of the calcium evidence is more
2 sanguine than FDA's with regard to the benefits of calcium
3 with regard to blood pressure.

4 Unlike the evidence regarding sodium and
5 hypertension, the literature on calcium has been consistent
6 and positive associations in the epidemiological literature.
7 Unlike the sodium and hypertension literature, while some
8 subjects derived great benefit than others, there does not
9 seem to be evidence of blood pressure increases with
10 increases in calcium, as there is in sodium.

11 And unlike sodium and hypertension, where there's
12 evidence of publication bias, the estimates from the
13 observational studies predict remarkably well the outcomes
14 of the randomized controlled trials.

15 So FDS was presented with evidence of improved
16 blood pressure response in both interventions--in low sodium
17 and in high calcium. But FDA sustained the health claim for
18 sodium and hypertension when the best meta-analyses found
19 falls of 1 millimeter or 1.2 millimeters mercury and the
20 long-term trials of hypertension prevention was 0.6
21 millimeters, whereas they rejected the calcium and
22 hypertension health claim when the best meta-analyses found
23 falls of 1.27 and 1.44.

24 So what's wrong with this picture? We've got
25 quite a bit of inconsistency and it illustrates our concerns

1 about our inability to evaluate health claims when we have
2 evolutionary scientific understanding.

3 Further, FDA is required to base a health claim on
4 that evidence which is currently in effect. And because
5 science itself evolves, government policies can become
6 outdated and a policy which no longer enjoys significant
7 scientific agreement should not be considered in effect and
8 therefore serve as a basis for a health claim.

9 We consider sodium to be a perfect example and
10 hope that the National Academy of Sciences can find the
11 resources to get back to what is now well over a decade old
12 finding which we don't consider any longer sustained in the
13 science.

14 We believe that Congress expects FDA to impose the
15 same high standard under FDAMA to allowable authoritative
16 statement health claims, but unless FDA can bring some
17 clarity and consistency to the way it administers the
18 program internally, claims based on authoritative statements
19 by outside bodies will create a quagmire for FDA and
20 confusion or chaos for the public.

21 It's crucial that FDA apply the same high standard
22 for health claims the agency has adopted by regulation so
23 that health claims that are not representative of
24 significant scientific agreement at the current time can be
25 revisited and, if appropriate, withdrawn.

1 In conclusion, FDA faces a great challenge
2 implementing FDAMA while enforcing high standards to protect
3 consumers against misleading nutrient health claims,
4 nutrient content claims or health claims.

5 The first priority should be to revisit and
6 resolve the current inconsistent standards which FDA has
7 used to approve health claims under NLEA. Then, with those
8 standards consistently enforced, FDA should expect
9 identified authoritative statements to meet these same high
10 standards. Lowering the standards or applying them
11 inconsistently ill serves the consumer and undermines the
12 validity, legitimacy and ultimately the credibility of
13 approved claims. Thank you very much.

14 MR. LAKE: Thank you.

15 The next speaker is Lisa Katic, director,
16 scientific and nutrition policy, Grocery Manufacturers of
17 America.

18 MS. KATIC: Thank you, Bob, and thank you to FDA
19 for the opportunity for the Grocery Manufacturers to present
20 our views to you today.

21 And out of sympathy for the panelists and all of
22 you attendees in the audience, I will be brief today. I
23 know it's been a long day but a very excellent, I think,
24 panel and discussion this morning.

25 For those of you that may not know, GMA is the

1 world's largest association of food, beverage and consumer
2 product companies. We have sales of more than \$450 billion.
3 GMA members employ more than 2.5 million workers in all 50
4 states. We are led by a board of 44 chief executive
5 officers and we speak--GMA speaks for food and consumer
6 product manufacturers at the state, federal and
7 international levels on legislative and regulatory issues.

8 Related to the forum today, certainly GMA and its
9 member companies have a deep interest in the use of truthful
10 and nonmisleading disease prevention claims and nutrient
11 descriptors based upon authoritative statements by federal
12 health agencies and the National Academy of Sciences.

13 GMA and its member companies urge FDA to use this
14 occasion to reconsider and revise its approach to the use of
15 truthful and nonmisleading health claims in food labeling.

16 As we've reiterated many times, and they say
17 repetition is certainly how you learn and if you don't know
18 by now, what we're talking about in authoritative statements
19 certainly expresses the clear intent of Congress to extend
20 available health claims for foods beyond those formerly
21 adopted by FDA.

22 Congress intended that FDA's role in the use of
23 health claims, based on the statements of authoritative
24 bodies, to be largely ministerial. As such, Congress did
25 not anticipate or encourage FDA to provide advice and

1 consent to its sister agencies, such as NIH and the Surgeon
2 General's Office, in the deliberations of those bodies
3 relating to diet and disease.

4 Instead, FDA's role is to establish processes and
5 procedures to facilitate the adoption of health-related
6 statements on food labels which accurately reflect such
7 authoritative statements without substantial health risk to
8 the American consumer.

9 GMA encourages FDA to recognize and implement the
10 intent of Congress to establish workable mechanisms for
11 prompt evaluation of claims submitted to the agency and to
12 promote the responsible, and I emphasize responsible,
13 development and use of authoritative statements.

14 I'm just going to summarize three areas that have
15 been pretty well discussed already today, and that's
16 authoritative statements, the context issue, as well as
17 significant scientific agreement.

18 As far as authoritative statements, Congress did
19 not unduly limit the source of an authoritative statement
20 other than, and I repeat again, that it must represent the
21 position of an agency and not an individual. I won't say
22 any more about that.

23 And I think this is stated in the Senate committee
24 report, and in quotes. "Important federal public health
25 organizations as part of their official responsibilities

1 routinely review the scientific evidence pertinent to diet
2 and disease relationships and publish statements developed
3 through such reviews."

4 I think some examples were discussed earlier or
5 given. I would also like to emphasize one that was
6 mentioned. The Heart, Lung and Blood Institute would
7 certainly be an appropriate body making recommendations on
8 cardiovascular disease or high blood pressure. Also, the
9 National Cancer Institute, which was already mentioned,
10 would certainly be appropriate to be making recommendations
11 on certain types of cancer.

12 As far as context, a statement labeled as a draft
13 or a preliminary review would not qualify as an
14 authoritative statement because of the context of that clear
15 classification. Now having said that, the context of a
16 statement in an agency publication will, of course, be
17 determinative of the type of claim that can be based upon
18 that authoritative statement.

19 For example, a carefully worded and qualified
20 authoritative statement may be accurately and truthfully
21 conveyed in any claim based upon it. On the other hand, a
22 broad and sweeping authoritative statement will justify only
23 a broad and sweeping claim.

24 Thus, the context of an authoritative statement is
25 of far greater importance in determining the type of claim

1 that can be made than it is in determining whether the
2 statement is authoritative.

3 Related to significant scientific agreement on
4 authoritative claims, we say that even preliminary findings
5 that reflect a general consensus of an authoritative body
6 are an acceptable basis for a properly qualified health
7 claim.

8 For example, an initial finding by an
9 authoritative body which indicates that people who consume
10 diets high in a particular food or nutrient show lower
11 instances of a certain disease or condition is sufficient
12 justification for an appropriately qualified claim, even
13 though such a finding may be characterized as preliminary
14 and in need of additional supporting information.

15 FDA's role under such circumstances should not be
16 to assert that no statement can be made. Instead, the
17 agency should encourage such statements while assisting the
18 regulated industry in assuring such claims are appropriately
19 qualified.

20 This is the role contemplated by FDAMA and the
21 role mandated by recent judicial decisions, of course
22 Pearson, applying well settled legal commercial speech
23 protections under the First Amendment.

24 This is the conclusion of my statement. We've
25 certainly provided further comments in written form to the

1 docket. Thank you again.

2 MR. LAKE: Thank you.

3 The next speaker is Ronald M. Lawrence, executive
4 director of the Council on Natural Nutrition.

5 DR. LAWRENCE: Thanks to the FDA for allowing me
6 to make this short comment today.

7 The Council on Natural Nutrition is a nonprofit
8 council which has three major goals. I, as the executive
9 director, my name is Ronald Lawrence, M.D., Ph.D., formerly
10 having served on the National Advisory Council on Aging and
11 also on the advisory board of ADAMHA, well familiar with the
12 intricacies and difficulties of government in arriving at
13 decisions, appreciate this opportunity to address you.

14 The three aims of the Council on Natural Nutrition
15 is to one, educate physicians about supplements, vitamins,
16 herbals. It's a big area. Number two, to educate the
17 public in a likewise fashion.

18 And number three, to encourage the type of actions
19 that are being taken in regard to this particular subject
20 that we're talking about here today, which is to guarantee
21 content and to in some way relate these natural products,
22 which are now becoming close to a \$20 billion industry and
23 growing all the time, so that we, as consumers, and
24 particularly those of us who are in the age category that
25 I'm in, with many of these people not having much money but

1 going out, as many as two out of three of those people,
2 which has been proven and which I think the FDA should
3 consider, two out of three Americans, particularly in the 55
4 and above age group, are going out and spending their hard-
5 earned money and are looking for guidance.

6 But also under the situations developed at the
7 NCI, the National Cancer Institute, where after years of
8 research to "cure cancer," now comes out with statements
9 that prevention is where it's at, and we believe prevention
10 is where it's at, and that the FDA, being an arm of
11 government, has a responsibility to reduce disease in any
12 way, shape or form, particularly if there are no great
13 dangers associated with that. And in that way we are
14 particularly concerned about the authoritative statements
15 and how they will be arrived at.

16 And, as I told you, I have served in government so
17 I am particularly concerned about that. These decisions may
18 take years and years. For example, with vitamin E, 50 years
19 ago we knew what it would do. It is only less than a decade
20 that we now, with the approval of government, accept the
21 concept that vitamin E is important in regard to prevention
22 of heart disease and circulatory disorders, et cetera. Do
23 we have 50 years to wait?

24 As a concerned citizen, not only for our
25 government and the money that is going--heck knows, I take

1 care of most of my practice in Medicare patients and the
2 money being poured into that and going nowhere in many
3 instances, we have to reduce that great burden. It is in
4 prevention that we'll reduce that burden.

5 So authoritative statements, and I'll wrap it up
6 here, we must take into consideration the industry, as well
7 as governmental situations. And I would recommend to this
8 committee that in some way scientists who are accredited
9 scientists, and that we can determine pretty easily--among
10 many who sit here are scientists. It isn't difficult to
11 determine whether someone is a creditable scientist. And in
12 science, we argue both sides of the issue. Science, even
13 though the public doesn't realize it, is not clear-cut. The
14 winner is the 51 percent. When you down 51 percent of your
15 opponents, then your scientific theory will prevail.

16 So we must have outside input in regard to
17 authoritative statements. In that way, and there is a way
18 to develop this within the confines of the bill, and that is
19 something that has to be addressed. In other words,
20 scientists who are not only serving presently on these
21 bodies, these governmental bodies, but scientists outside
22 these bodies who are creditable scientists should have input
23 into this very important situation.

24 I thank you for allowing me to address you.

25 MR. LAKE: Thank you.

1 The next speaker is Stephen D. McCurry, manager of
2 biochemistry for Research-Based Dietary Ingredient
3 Association.

4 MR. McCURRY: Thank you very much. I want to make
5 a small correction to that introduction. The Research-Based
6 Dietary Ingredient Association is a small group. We have no
7 professional staff. That's actually my Cargill title rather
8 than any title--in the trade association, I'm coincidentally
9 treasurer, but that's kind of irrelevant to these comments.

10 The Research-Based Dietary Ingredient Association
11 formed about a year ago. It's a small group of companies
12 committed to championing the role of science in the
13 development of functional food ingredients and related
14 products. We believe it's essential for science-based
15 companies to take the lead in establishing and abiding by
16 standards for scientific research, to assure product safety,
17 substantiate claims and assure consumer trust.

18 I really appreciate this opportunity to come here
19 today and make these remarks and I will keep them short, in
20 tune with the end of the day, and a lot of this has already
21 been said.

22 We have submitted comments to this that address
23 some of the FDA's questions in some more detail. I'd like
24 to take this opportunity to offer some perspectives on
25 closely related issues that are really part of this whole

1 topic that we've talked about today but haven't directly
2 talked about.

3 Several speakers today have talked about the fact
4 that this is complex and important legislation. We
5 certainly agree that it's very important. The complexity
6 has been talked about a lot today and there certainly seems
7 to be, from the regulatory side, a great deal of complexity
8 to the issue.

9 If I were speaking just as a consumer, I might
10 think it was a little simpler topic. I would say something
11 like I really want to know if the product is safe and if it
12 does what it says it does and if that's good for me.

13 There are a lot of ways to address this topic.
14 One of them is by the means of FDAMA. There are several
15 others that are not the topic of today's meeting and I'm not
16 going to talk about those.

17 RDIA believes that the scientific issues are
18 common across these different ways of addressing the
19 question that the consumer is interested in. We believe
20 that consumers have the right to know that the foods and
21 dietary supplements they consume are safe and that the
22 claims made about them are truthful and not misleading.
23 This would be a hard statement to argue with, I think.

24 We believe that there are two fundamental
25 principles that should guide all aspects of research and

1 development of ingredients in the food and supplements
2 industries and the products in which they appear.

3 First of all, whether they're conventional foods,
4 dietary supplements or new dietary ingredients, the products
5 should meet a common safety standard and that their
6 consumption will not pose a significant or unreasonable risk
7 to health when used as intended in the population for which
8 the product is intended.

9 And I want to distinguish the use of standard here
10 from process because I think some of the confusion sometimes
11 gets them mixed up together. Meeting the standard may
12 require a scientific process similar to that used to
13 demonstrate that a product is safe, that a product is GRAS.

14 For example, if the safety assessment of a new
15 dietary ingredient in a dietary supplement indicates the
16 safety standard listed above, that there's not enough
17 information for it already in the literature or in prior
18 public use, then some form of safety research is going to be
19 needed to demonstrate the safety.

20 We believe there's a need for uniformity of
21 understanding in the industry as to what this safety
22 standard means and what information is required to be
23 assured the standard is met. While DHEA does not require
24 the GRAS process, neither does it excuse any company from
25 providing products that are safe for the target population

1 at the specified level of ingestion.

2 RDIA's goal is to help establish within the
3 industry uniformity in understanding what information are
4 science are required to meet the safety standard, as
5 indicated by law.

6 The second fundamental principle is to the other
7 side of this. Any type of labeling claim made about food
8 ingredients or dietary supplements should be based on
9 competent and reliable scientific evidence that establishes
10 its truthfulness to a reasonable certainty. In addition,
11 RDIA believes that products whose benefits to health have
12 been demonstrated by sound scientific research to a
13 reasonable certainty should be able to describe these
14 benefits in labeling and via other means of communication.

15 We see no rationale for differing standards--there
16 are different processes but not different standards--of
17 substantiation for labeling claims for either foods or
18 dietary supplements. The nature of the science needed to
19 support a claim likely will vary, depending on the type of
20 claim being made, but the same standard of reasonable
21 certainty that the claim is truthful and not misleading
22 should be required.

23 We further believe that claims about the
24 physiological effects of foods and supplements should be
25 allowed, providing they do not state an ability to prevent,

1 cure or treat a disease regardless of the biomarker status
2 of the particular health condition.

3 Currently the food and dietary supplement
4 industries are developing products with claims based on new
5 data at a pace that exceeds the abilities of the FDA, with
6 its limited resources, to review them expeditiously. We
7 believe there are other approaches to this and I'll offer
8 one example, just as an example.

9 A process similar to that used for private GRAS
10 assessments could be applied for claims evaluation. A
11 company could seek evaluation of an independent body of
12 experts to provide an unbiased opinion of the adequacy of
13 the data. A body such as the Life Science Research Office,
14 for example, or other organization of similar stature could
15 do this. It could be considered as an independent expert.
16 Claims determined to be adequately supported could be
17 distinguished on labeling.

18 This option would take much of the burden of data
19 evaluation off of FDA. And if such a process were done
20 voluntarily by the manufacturers, we would even say that FDA
21 could exercise its own authority under FDAMA as the
22 authoritative body to authorize a health claim on such
23 research.

24 Those are the only comments I have. If you want
25 to see a slightly longer document, you can get the comments

1 we turned in. Thank you.

2 MR. LAKE: Thank you.

3 The next speaker is Michael McGuffin, chair of the
4 Government Relations Committee, American Herbal Products
5 Association.

6 MR. MCGUFFIN: Thank you very much. And again
7 thank you to FDA for sponsoring this. It's really a good
8 forum for this kind of discussion.

9 My name is Michael McGuffin. I am here today on
10 behalf of the American Herbal Products Association or AHPA.
11 AHPA is the trade association of manufacturers of herbs and
12 herbal products, including dietary supplements.

13 I would like to offer comments on three particular
14 points related to today's discussion from the perspective of
15 herbal dietary supplements.

16 First, AHPA is aware that FDA has proposed to
17 permit the use on dietary supplements of health claims based
18 on authoritative statements under the notification
19 procedures in FDAMA. AHPA agrees that health claims based
20 on authoritative statements should be allowed for dietary
21 supplements and therefore agrees with FDA's conclusion in
22 this regard.

23 However, AHPA notes that all of FDA's NLEA and
24 FDAMA health claims implementing regulations must be
25 reevaluated to consider the recent mandate and decision of

1 the U.S. Court of Appeals in Pearson versus Shalala.

2 Secondly, AHPA wishes to express its concern
3 regarding one particular definitional limitation of FDAMA.
4 By defining authoritative bodies to include only a
5 scientific body of the U.S. government that has official
6 responsibility for public health protection or research
7 directly relating to nutrition or the National Academy of
8 Sciences and its subdivisions, any information that comes
9 from scientific bodies that may have such responsibilities
10 in other countries is irrelevant to the establishment of a
11 scientific basis for a legitimate health claim.

12 In an era when communication is nearly
13 instantaneous and when international harmonization has been
14 accepted as a valuable concept, this is an unfortunate
15 limitation. Because almost all of the contemporary research
16 on herbs has been conducted outside of the United States,
17 this is particularly unfortunate for consumers of herbal
18 products.

19 AHPA is aware that in identifying this last
20 statutory limitation inherent in the language of FDAMA, it
21 has identified a concern that is outside of the scope of the
22 authority of the U.S. FDA. Nevertheless, it is important
23 that we're all aware of the fact that the current laws and
24 regulations of the United States do not allow consumers of
25 herbal dietary supplements to have straightforward access to

1 all of the scientific information that might assist them in
2 making choices about their health. Until such time as this
3 limitation is addressed, AHPA intends to continue to work
4 closely with FDA and the legislative process to attempt to
5 correct this defect.

6 Finally, there is one additional related issue
7 that demands comment. In the dietary supplement proposal
8 published in the Federal Register on December 28, 1995, FDA
9 sought to clarify the agency's thinking with regard to the
10 relevance of health claims for nonnutritive substances. It
11 concluded at that time that "nutrients that are the subject
12 of Section 403(r)(1)(B)," that is, nutrients subject to
13 health claims, do include vitamins, minerals, herbs and
14 other nutritional substances.

15 This position was reiterated in the coverage
16 accompanying the final rule for requirements for nutrient
17 content claims, health claims and statements of nutritional
18 support for dietary supplements published in the Federal
19 Register on September 23, 1997.

20 AHPA supports the agency in maintaining this
21 position and, in fact, would consider the opposite position
22 to be a serious flaw in providing meaningful, health-
23 promoting information to consumers of the broad range of
24 dietary supplements and particularly herbal dietary
25 supplements.

1 Thank you very much for your attention and thank
2 you again to FDA.

3 MR. LAKE: Thank you.

4 The next speaker is Dr. R. William Soller, senior
5 vice president and director of science and technology for
6 Consumer Healthcare Products Association.

7 DR. SOLLER: Good afternoon. I'm Dr. Bill Soller,
8 senior vice president and director of science and technology
9 for the Consumer Healthcare Products Association and with me
10 here today is Miss Eve Bachrach, general counsel for the
11 association.

12 CHPA, formerly the Nonprescription Drug
13 Manufacturers Association, represents producers of quality
14 dietary supplements and nonprescription medicines, including
15 over 200 member companies across the manufacturing, supply
16 and service sectors of the self-care industry.

17 Our comments have been submitted to the docket and
18 I've just handed you copies and I will make three basic
19 points from them, and I'd like to add one postscript, if I
20 could, based on the discussions.

21 First, we support application of the authoritative
22 statement provisions of FDAMA to dietary supplements.
23 Second, FDAMA Section 303 explicitly stipulates criteria
24 defining an authoritative statement, and FDA should not
25 expand these criteria so as to supersede a qualified

1 scientific body making an authoritative statement.

2 And third, FDA review of health claims and
3 nutrient content claims based on authoritative statements
4 should be a three-step process that emphasizes confirmation
5 that an authoritative statement has been issued by a
6 scientific body, not scientific rereview and approval of
7 that authoritative statement. And I'd like to amplify on
8 this last point.

9 Now it all starts with an authoritative statement
10 from a scientific body of the U.S. government with official
11 responsibility for public health protection or research
12 directly relating to human nutrition or the NAS, and we
13 would say possibly other appropriate organizations, and it
14 would make sense to us, based on discussions we heard today,
15 to expand this to appropriate centers within these
16 organizations, such as NIH.

17 But in any case, the authoritative statement is
18 the presumptive surrogate of an FDA deliberative process,
19 leaving FDA with an authorization role in a three-step
20 process.

21 Step one would be the notification of FDA by
22 submission about a health claim based on an authoritative
23 statement under the statutory 120-day procedure. FDAMA
24 elaborates the components of this notification, which should
25 not include detailed scientific data and information as

1 might be submitted for de novo development of an
2 authoritative statement by FDA itself.

3 Step two is the confirmatory step where FDA would
4 first determine if all the components, per 403(r)(2)(G) and
5 (3)(C) are present, where FDA would then determine what
6 nutrient is at issue and confirm the authoritative statement
7 is attributable to a scientific body and is published per
8 403(r)(2)(g) and (3)(C), and where FDA could then, as
9 needed, contact the scientific body and confirm the
10 authoritative statement is currently in effect and determine
11 that the statement is not by an employee in his or her
12 individual capacity, again per FDAMA.

13 Now step three would be the authorization step,
14 where FDA would review the claim so that it is an accurate
15 representation of the authoritative statement, including its
16 context, and so that it is able to be comprehended by the
17 public, including its relative significance in the context
18 of the total daily diet, again from FDAMA. And part of this
19 authorization step would obviously be notification of the
20 petitioner and public.

21 Importantly, this three-step process is basically
22 outlined in the statute and does not have FDA invoking a
23 significant scientific agreement standard per se to evaluate
24 a scientific body's authoritative statement. To do so would
25 overengineer FDAMA, certainly the regulatory implementation

1 of it by FDA, and it would run counter to congressional
2 intent to have an alternative mechanism to streamline and
3 expedite health claims authorization.

4 Clearly the confirmation step where FDA could, as
5 needed, contact the scientific body and determine that the
6 authoritative statement is current and not the statement of
7 an employee in his or her individual capacity is the
8 appropriate level of regulatory oversight, consistent with
9 the statute, to ensure the claim is appropriately supported
10 and attributable to the scientific body and/or its centers
11 or institutes.

12 In sum, there is no basis for an independent FDA
13 review of the science that has already been reviewed by
14 another federal government scientific body. FDA
15 reexamination of the claim under an NLEA significant
16 scientific agreement standard would basically bootstrap the
17 NLEA standard and procedure into the FDAMA procedure. It
18 would mean that FDA could substitute its own judgment for
19 the authoritative statement of another federal government
20 body, effectively gutting the FDAMA provision. And this
21 would produce a repetition of the problem represented by the
22 folic acid situation, which the FDAMA provision was intended
23 to correct.

24 Now I'd like to add my postscript, if I may, based
25 on the discussions. I think that there is no such thing as

1 a qualified authoritative statement. An authoritative
2 statement is a statement from an authoritative scientific
3 body. The authoritative statement is based on data and
4 information where in probably almost every case the science
5 is not absolute.

6 The authoritative statement, however, as it is
7 written, can be definitive in nature and potentially, as we
8 think we've outlined in the three-step process, the
9 situation for FDA authorization could be relatively
10 straightforward.

11 Or we think it could also be a judgment about
12 persuasive data in terms of a diet-disease relationship and
13 as such, some health claims may appropriately bear a
14 disclaimer as part of the statutory requirements of
15 truthfulness and accuracy.

16 The basis for such a disclaimer is obviously tied
17 to the First Amendment commercial speech doctrine reflected
18 in Pearson v. Shalala, as well as the Washington Legal
19 Foundation on drug claims about unapproved uses.

20 So the challenge to FDA is to embrace procedures
21 that facilitate satisfying this tremendous demand that
22 consumers have for health-related information for personal
23 decisions about self-care and product choices. The food and
24 dietary supplement product label is where this should
25 happen, with or without appropriate disclaimers, per the

1 statute and per the Constitution. Thank you.

2 MR. LAKE: Thank you.

3 Our final registered speaker for this afternoon is
4 James S. Turner, Esquire, chairman of the board of Citizens
5 for Health. He's with Swankin & Turner. Is Jim here?

6 VOICE: He's in court and he wasn't sure he could
7 be here.

8 MR. LAKE: Oh, I see. Is there perchance anyone
9 in the room on his behalf?

10 [No response.]

11 Okay, well I guess that is the end of that.

12 Let me say that we did not build into the schedule
13 an opportunity to question the presenters during this last
14 session. I would, however, encourage the speakers to linger
15 a bit after the meeting is over so that if people have
16 questions of you, that they may get them answered.

17 I guess with that, let me turn to my colleagues as
18 to whether there's anything else that--okay.

19 Let me start by thanking them. They've been
20 terrific support for this. Let me also thank the other
21 people who helped with the registration, the collection of
22 the cards, et cetera.

23 And again let me thank the USDA for providing the
24 auditorium and their staff for helping us with the
25 arrangements here this afternoon.

C E R T I F I C A T E

I, **SUSAN A. HARRIS**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in cursive script that reads "Susan A. Harris". The signature is written in black ink and is positioned above a solid horizontal line.

SUSAN A. HARRIS