UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD AND DRUG ADMINISTRATION

FOOD ADVISORY COMMITTEE MEETING

Holiday Inn-Eisenhower Metro Center
2460 Eisenhower Avenue
Alexandria, Virginia

September 26, 1997
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C O N T E N T S

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P R O C E E D I N G

(8:30 a.m.)

ADMINISTRATIVE

CHAIRMAN BRANDT: Okay. Good morning, I hope everybody had a pleasant evening and are ready to go back to work. The working groups will convene, or two of them at least, the Emerging Sciences Group and the Incentives Groups, I guess it is. As usual, we will begin with administrative stuff.

Dr. Larsen?

DR. LARSEN: This will be short relative to some of them I've had. I will let Dr. Brandt introduce our speaker this morning, but I share a carpool with the gentleman who wasn't able to make it yesterday, Mr. Bob Lake. He is not only my boss, but he is in my carpool.

He finally made it home about 8:30 or 9:00 last night, and we talked a bit before he picked up his car, since we meet in front of my house, and he guaranteed me that he will be here at 9:00 to talk about the Senate bill on FDA reform and to tell us what happened in the committee yesterday in the House on the FDA reform bill on the House bill.

I noticed by the headlines -- I shouldn't say the headlines, but in the second page of "The Post" this morning that there is a big article on FDA and imports. I know until the newspaper this morning we couldn't talk about that. I don't know how much Bob can talk about it, but I know he has been involved, so we may put him on the spot for a few minutes to see what he can say publicly in addition to whatever the newspaper may have said about that issue.

I have been informed that there will be a November meeting. I don't know what the topics will be yet. We still have to find a place to hold the meeting. I don't know whether we will use the full three days; I doubt it, but it is possible.

So, those three days that we had you set aside, at least tentatively on your calendars, if you would, try to keep them open. We will inform you. It is the Wednesday, Thursday and Friday the week before the week of Thanksgiving. I think it is the 19th through the 21st, okay, of November, right. As soon as we know and can tell you what it is all about, we will let you know. I believe that takes care of it.

Again, the Incentives Group and the Emerging Science Group will meet after the committee adjourns. I have a few administrative comments for the Emerging Science Group. I have already delivered the Incentives Group theirs yesterday when they met in a session in the late afternoon since they had extra time.

CHAIRMAN BRANDT: Okay. Any questions about any of that? Everybody ready to begin?

Okay. Let me present to you Dr. Nancy Childs, who is from the Department of Food and Marketing at St. Joseph's University and she is going to give us results of a survey of the food industry relative to incentives.

ACADEMIC SURVEY OF INDUSTRY INCENTIVES

DR. CHILDS: Good morning. I want to thank you for the opportunity to be here. I am going to share some highlights from a study that was conducted jointly with the University of Illinois and myself, funded by the Functional Foods for Health Program. We are a small group and I welcome any questions at any point, again just to identify the research.

The survey was initiated basically to assess industry attitudes towards a need for research incentives.

CHAIRMAN BRANDT: Everybody ought to have a copy of the slides.

DR. CHILDS: The Functional Foods for Health has an industry support group, and so it was really coming out of some interest there and exploring the incentives particularly taking the

issues that were introduced in the Keystone Dialogue and trying to get a wider set of opinions on that. We are also trying, in the research, to see if there were differences by industry, by function of respondent, particularly R&D versus marketing management, and what we call a "chain-to-market" approach.

Simply to refresh everyone, the Keystone Dialogue introduced six concepts very briefly, just at the exploratory level: the exclusivity concept, which would be also referred to as a proprietary health claim where the company that invests in the research and receives the claim approval would have the exclusive right to it in the marketplace for a set period of time.

A lead time to market, where the company that gets approval of the health claim has preapproval knowledge, hence they could develop a marketing plan, a launch plan, et cetera, in advance of the announcement of the health claim.

Tax credits, we looked at a compulsory health claim royalties format much like was used in FIFRA, but again just like the concept of that where the company who was awarded the health claim would have the right to solicit royalties from other companies with qualified products who use the health claim.

An orphan drug model, which is a combination of exclusivity, research support, claim approval, and tax credits. Then research pools, which are very similar to what we see with your large agricultural commodity boards and that type of format. Then, of course, we have our existing generic claims.

I have made available to the committee a copy of the questionnaire, and in the questionnaire we have detailed the definition on each of those alternatives. This is, of course, available to be explored by anyone who is interested. Our target market, or our target audience, were the individuals from companies marketing or intending to market functional foods.

This was really a very large data base owned by the Functional Foods for Health program. We distributed close to 2,000 surveys to about slightly less than 1,200 individuals because there were some multiple mailings to get responses. We, I think, conservatively had a 16 percent yield. I say "conservatively" because it does not take into account that a number of these questionnaires went to individuals who were not at all involved in the category and may count for some of the nonresponses. At any rate, for a mail survey of this magnitude, that is a response rate that is considered average and normal.

Of the industries that responded, we had 55 percent of the sample coming from the food industry, 13 percent from the pharmaceutical and 32 percent from the dietary supplement industry. I do want to say that the lower pharmaceutical participation is not low participation by the industry, but the fact that it is a smaller industry in terms of the number of companies to approach.

If you look at what we call a "chain-to-market" concept, we are finding that we had about 11 percent in seed agriculture, 38 percent ingredient supplier, about 46 being the manufacturing level, and then 17 percent on the direct marketing retail level. That does add slightly larger than 100 because some companies were multiclassified.

But again, I thought that ended up being a fairly good representation of a chain-to-market. We also wanted to look at size of company. We had about a quarter of the sample being 50 million or smaller and not quite two-thirds being over 50 million.

These are our highlight of results. I think the kind of overreaching result, in terms of comparing the different incentive formats, was a very strong preference for exclusivity with an orphan drug model format, which certainly has exclusivity components to it, being the in the first

and second place. We found that the lead time, compulsory royalties, tax credit, and research pools dropped further down.

We explored a number of questions that from my perspective, and I am in the Department of Food Marketing in the School of Business at St. Joseph's. I wanted to get a handle on the differences of the incentive impacts on private versus public goods, so to speak, in terms of incentive formats to bring back private benefits and do those formats bring back public benefits or do we have differences here. As an academic looking at it, I tried to explore that angle as well.

I am going to ask you to ignore the other column, because it is simply too small a sample to be worth attention. What we found, again, is that across the three major industries in the study of food, pharmaceutical and dietary supplement, very strong preference within each industry for exclusivity. That was very significant results. We are insignificant comparing industries on this issue. In other words, they are alike in that preference.

When we wanted to ask them about whether it would increase market share, the prior one, of course, was asking about increasing profits. Again, we got very similar response in that they saw exclusivity far and away as a stronger way to increase your individual firm market share.

We did get different results when we asked about growing the category overall. Here we had some differences in that, for the food industry, research pools were looked at as a more effective way to grow the market. That is not unfamiliar because research pools in commodity groups have existed in the food industry for a long time, different agricultural groups. I think that reflects what has been an existing and ongoing model.

I thought it was interesting looking at pharmaceuticals. They still felt that the generic claims would grow the market the most as well as again complimentary to claims, the idea that the orphan drug would. That, to me, is a very complimentary response. Dietary supplements, also seeing a lot of attention to the generic claims themselves as well as exclusivity.

In terms of growing the category by size of respondent, we were also interested in an entrepreneurial variable, we really didn't pick up any significant difference here. I was intrigued again by the big companies seeing so much value in the research pools.

Again, this was another one of those larger questions simply asking the importance of a health claim to the profitability of a functional food. What we are seeing is on a proprietary claim a very high level of importance, and a lower level of importance on your generic claim format, your existing format. But that still is a pretty high response. You have got about half of the population feeling there is importance in the existing status quo, but they would find that to be increased if we moved to a proprietary format.

Then we asked questions a number of ways and in a number of places, so the questioner felt the results were pretty consistent across them. We wanted to know who should award exclusivity.

We found very high response among the government alternatives with the FDA/DHHS format, that that would be the preferred agency if it was a government agency. Two-thirds of the sample felt it should be a government agency making that award, one-third felt it would come out of the private sector. That will be my next slide.

I do want to say, though, that there is significant difference between the responses here on marketing and research personnel at about the 93 percent level. We are getting a little bit of difference in terms of who the respondent is and what kind of corporate responsibility we carry.

As we go through the data, that is one of the largest findings that fell out of this was, that

depending on whether you are in the organization asking the marketing side as opposed to the research side, you do tend to get different responses on the value of exclusivity and the impact of different exclusivity as well as other claims.

To me as an academic, that is an interesting organizational issue in terms of where it is correct to collect the data and whose perspective we want to really take lead here. To me this was one of the overriding conclusions of the study.

We found on some issues significant difference by the industry of the respondent. I have kind of reached a personal conclusion here in that I feel the food industry may be ready for functional foods, but I am not sure the food industry is ready for the functional food industry in that it puts them in partnership with the pharmaceutical industry and the dietary supplement industry.

As we move through this, you will start seeing they definitely have different perspectives on what the barriers are in the marketplace and what their competitive advantages are in the marketplace. I am sort of interjecting that now, but I think overall these were two important findings for me.

This is going to be a much harder group to draw consensus from because they have had very different experiences with regulation. This is also, again, very significant by research and marketing results. But again, of those who want to have a nongovernment approval that third of the sample research prefers use of independent experts; the other group tends to divide that across a wider range with emphasis on interested associations, that would be relevant associations to that group.

An issue that, frankly, came out as a bit of a surprise in this research and came out with very high rigor was learning that the industries were interested in a government-recognized definition. Again, we see that pretty clearly across the industry. Dietary supplement being less enthusiastic but still giving that a majority.

Two-thirds of our food industry respondents, almost three-quarters of our pharmaceutical industry respondents, saw value in a definition, a government provided definition for the category. Accompanying that finding is their desire for a regulatory pathway for functional foods.

Again, we are seeing very strong results out of pharmaceutical and that tapering across, dietary supplements again showing a majority but with less enthusiasm. What I am seeing here is a pharmaceutical industry that is very comfortable dealing with a very regulated environment, a very carefully and cleanly defined environment for product approval.

They are taking that mind-set as they move into this industry. This is not the mind-set that we are finding in the food industry to the same degree, and it is not the mind-set that we are finding in the dietary supplement industry which tends to be much more entrepreneurial in its approach and of course is under a different set of regulatory requirements on their labeling right now.

Again, do we think having a pathway would increase the likelihood of investment? Again, we are getting significance here above the 90 percent level, not 95; but again, we are seeing the same kind of differences with the exception of dietary supplement who do not see that having such impact.

When we talked about exclusivity, we wanted to know how many years; what do you think. We did seem to get a spike on five years in terms of how the industry looked at what would be the preferred number.

Now, getting back to these issues of definition for functional foods, government definitions and pathways, we explored these looking at who was the respondent. We get highly significant difference again on whether you are talking to a research personnel or a marketing personnel.

Again, your research person is much more likely to see value to prefer having the formal regulations, and that is not true on the marketing side. Again, we are seeing this difference in terms of who you speak to. In terms of a regulatory pathway, we do not pick up significant difference. In fact, they on this particular issue tend to have a very similar response.

But again, seeing the strong, I think, tendency for risk reduction, would this increase your likelihood of investment? Again, we are not getting significant differences on this. But R&D, though it is not a significantly different response at a 95 percent level, clearly there is a belief on the R&D side that they would imagine that being so.

We asked a number of questions about barrier to the market, and I want to explore some of them. These were cost barriers, and they emerged as the greatest barriers. Again, the largest one being the cost of clinical trials. The blue here being the secondary position is your cost of R&D (indicating). These are seen as barriers to succeeding in this marketplace.

These are concerns that, when I did an industry study back in 1992, were the same barriers that surfaced then when this was certainly then very much an embryonic concept.

Your cost barriers take the lead position. These are followed by what we would call "regulatory barriers," and that is, concern about lead time to market because of regulatory issues and simply the uncertainty of a regulatory path. Again, we are seeing these taking on some major positions in the evaluation of them as barriers.

I wanted to look at these a little closer. Again, we are getting significant results if we look at the cost of clinical trials, these are significant about the 93 percent level where R&D views the cost of clinical trials as a larger barrier than their marketing colleagues. If we look at it by industry, then we are not getting significant results on this. We are seeing different responses.

In particular, you can see all the pharmaceutical industry, the yellow, does not see that as large a barrier as other industries. This is not an unfamiliar task for the pharmaceutical industry. This is not a daunting and scary thing, something that they are used to having in their cost budgets.

Again, when we talk about the barrier of the cost of R&D in the pharmaceutical industry, which has an enormous dedication of resources in R&D, it takes a much lower prevalence, again the yellow bar shifting much more to the lower barrier side. Again, for the food industry which operates on very tight R&D budgets, we are seeing that being a concern. This is a deviation in a direction they are not prepared for.

On lead time to market, we get extremely significant difference across the industry. They are all looking at this differently, and this is lead time to market, because of regulatory issues. That bothers the pharmaceutical industry. It doesn't bother the dietary supplements at all, and that is probably a reflection that they are under a different regulatory regime.

We asked about the lack of intellectual property protection, the barrier of that, in that the generic claims can be viewed that way. Of course, that is a key issue to the pharmaceutical industry because they are again used to the benefits of being in a regulatory environment. We see them taking the lead on that.

Again, looking by industry at the uncertainty right now of not having a regulatory path for approval, we get high significance by industry. Again, this uncertainty being a greater

concern in the food industry, falling back a bit on pharmaceutical, but again it is dietary supplement that is less concerned. I think because they are less impacted with that at present.

If we look at this question by function, whether you are marketing or R&D, you again get very high significant results, differences in terms of how the research person views the regulatory concern versus marketing.

We had a consumer question in here, and we asked you; what do you think the consumer would think in an exclusive claim environment where one product might carry that claim and another similar product would not. How do you feel the consumer would react to that?

We have just under three-quarters of the responses saying, we think the consumer would be interested and influenced to purchase by that health claim. We had about 10 percent saying, well, we think that they would see the interchangeability of the products. A very small level saying indifference. But one thing that does concern me personally is you run about a 12 percent level where the industry itself felt the consumer might be confused.

Simply, as summary here, we went back, and again this is the ranking of the different claims and how important industry feels they would be to them in obtaining success in the marketplace, and again one being the highest score, we are seeing in terms of importance the existing FDA approved health claim, a structure function claim or access to a proprietary claim, which of course doesn't exist at present, all being ranked at the top with the same result.

Falling down next to importance would be the medical claim and then falling towards the bottom of this relative ranking would be your DSHEA structure function as it exists now with the disclaimer, the nutrient discriptor, and the ingredient content claim.

The next steps, as far as this research goes, these are preliminary findings, "highlights," as I would like to call them, are that we are working to publish the research. There is certainly need for much more discussion on this issue. This is by no means a definitive and final study. We need to understand more about research issues and the regulatory and implementation issues.

To that extent, I want to say that the Functional Foods for Health program in Illinois is going to be holding a workshop on this in November to explore more what do we mean here, where are the industries coming from. In a lot of ways, this is a survey that is helping us ask better questions rather than yielding final answers.

I also want, at this point simply, to share with you that I will be on a panel of speakers at the ADA, the "American Dietetic Association," at the end of October where we will be exploring the panels called Functional Foods Therapies for the Future but I am using this data, particularly going back to specific questions asking about public health, about consumer education and trying to pull out those issues and the data.

I can make that available to the commission and the work group. I would be glad to. Again, we are finding research pools tend to be the format that industry thinks delivers the most consumer education on diet and health and would deliver the largest impact on public health in general. But exclusivity ranks second, a very close second there. I think that is interesting. That is coming up.

I just also want to mention, separate from that, that a colleague of mine in mathematics and I at St. Joseph's have received a very nice two year grant from the USDA to look at the incentive issues through a modeling format. I have made a first paper draft available to Lynn Larsen on some of our work there where we are trying to, again, from what we know about market dynamics, look at if you put different incentive structures in place, how do you alter the outcomes. That research has just begun, and that is a two year format.

I welcome any questions, and I thank you for this opportunity.

CHAIRMAN BRANDT: Thank you, Dr. Childs. Any comments? Yes, Dr. Harlander?

DR. HARLANDER: Can you tell me the sample size for R&D and marketing that you would have had in there? And, did you see any differences split out as to large company/small company?

DR. CHILDS: By and large, the large company/small company did not yield significant results, because we did explore for that. The chain-to-market variable we have not run rigorous statistics on yet, so I don't have results on that. I have to just look in here. I have that number and I can provide that for you.

DR. HARLANDER: Okay, thanks.

CHAIRMAN BRANDT: Yes, go ahead.

DR. ASKEW: Wayne Askew. A very interesting presentation, Dr. Childs. Your second from last chart showed nutrient descriptor claim as ranking relatively low. That is just nutrient content listed on the package?

DR. CHILDS: Mm-hmm.

DR. ASKEW: We had some results presented to us by some study that the USDA has done, Alan Levy has done, where the consumer, and I'm not talking about the company here but the consumer, ranks that much higher than the companies do.

DR. CHILDS: You are exactly right. I served on an advisory committee for that piece of research so I'm familiar with that. I think that is an important understanding, that these are industry perspectives. In this regard, industry may be undervaluing the communication value of that type of claim.

DR. BENEDICT: Steve Benedict. It is a small question. With respect to the large company/small company, do you have any information about who thought the public would be most likely to be confused?

DR. CHILDS: I would have to check that, and I would be glad to do that. I don't believe that was significant, but I can certainly recheck that issue for you on that split.

DR. BENEDICT: Thank you.

DR. CHASSY: Okay.

CHAIRMAN BRANDT: Any other? Yes?

DR. FUKAGAWA: Naomi Fukagawa. Do you have information about the 184 respondents with respect to whether or not they presently have products that use health claims or have something in the planning stage?

DR. CHILDS: They have to be either impending or in the market with a market they felt would enter the functional food, which is a big diverse definition. We did provide a definition there. That does not mean you are using a health claim and positioning it that way, but 100 percent of the qualified sample is in that category.

CHAIRMAN BRANDT: Yes. Go ahead, Ms. Richardson.

DR. RICHARDSON: Donna Richardson. Did the respondents indicate what the purpose of the incentives would be for them?

DR. CHILDS: Well, since this was a structured questionnaire, the questions where we allowed them to respond were profitability both of market share and both of market category. Those are where I have, what we might say, how do they view those motivations. We did not ask them if there were other motivations beyond that, because this was a structured mail survey.

DR. RICHARDSON: Thank you.

CHAIRMAN BRANDT: Other comments? Questions? Okay. Thank you very much.

DR. CHILDS: Just as a point of information for me, do I respond with some of these requests to the agency or directly to the individuals?

CHAIRMAN BRANDT: It doesn't make any difference. Give them to Dr. Larsen. He is always good at sending us stuff.

DR. CHILDS: Okay. That is fine. I would be glad to follow up on the questions. Thank you.

CHAIRMAN BRANDT: Thank you. Well, we are waiting on our next presenter who isn't here yet.

DR. LARSEN: There was a train just pulling in, so we hope he is on that train.

CHAIRMAN BRANDT: Well, let's hope so. Okay, so anyway we can stand down and relax for a few minutes, if you wish.

(Recess)

DR. ASKEW: At what point in time will we be given a further update on the Olestra, I don't want to say issue, but how it has been going, number of adverse cases reported, and so forth like that?

CHAIRMAN BRANDT: Yes. I think let's try to see if we can't do that in November.

DR. LARSEN: Let's put it this way. There was a suggestion by the staff, but for various reasons that I am not quite clear on myself and what little I do know I can't talk about, we postponed discussion of any update of Olestra at this meeting. I will talk to --

CHAIRMAN BRANDT: I am talking about November.

DR. LARSEN: Well, in November we will talk about that again. But I can say I am working with the staff of the Office of Premarket Approval. We are talking about when to arrange for the meeting that was promised in the final rule for the 30 month, yes, when it was finally published in January 1996. We promised that we would revisit the issue again in 30 months. That 30 months, depending on how you count, is either June or July 1998.

You can plan that there will be a meeting sometime in that time frame. As I was mentioning to Dr. Blackburn yesterday, if it does end up having to be July, half of the existing committee will have served their term. We may be coming back and asking you to re-up for a month or two, just so you can attend that meeting.

CHAIRMAN BRANDT: Then we close it?

DR. BLACKBURN: Are you sure you want to?

DR. LARSEN: At this point, there has been a lot of data submitted by P&G to the agency, and there has been a lot of data submitted by CSPI to the agency, and the agency is continuing to be in discussions with those two groups. Beyond that, that is all I know and that is about all I can tell you.

CHAIRMAN BRANDT: The answer is that it may happen, and then again it may not happen so we will just wait and see, I guess.

Any other comments, questions, anything?

All right. Does anyone from the audience have anything they would like to say to the committee?

A very quiet audience. Why, what a break. This is the first time this ever happened.

DR. LARSEN: Well, this is just about our speaker. He is here. He is on his way to the podium.

CHAIRMAN BRANDT: He is here. He just made it.

MR. LAKE: The real reason I walk in at the last minute is I keep telling Lynn Larsen that he just doesn't appreciate me. I figured if I made him pace the floor a little bit, then maybe that might change.

S.830; FDA REFORM AND THE FUTURE

DR. LAKE: Good morning. One reason I am a little bit late is I wanted to get clearance from Fred Shank that I could talk to you a little bit about this new initiative you may have read about in "The Washington Post," and he has agreed that I can do that. That was my last visit before getting on the subway, but there is still a lot swirling around that.

Let me first, though, talk a little bit about the FDA reform legislation, which was actually the intended topic. It turns out the timing is pretty good, because there has been significant activity here within the last couple of days. As many of you know, the issues, broad issues, of FDA reform have been hotly debated in both houses of Congress for the last couple of years.

Day before yesterday, the Senate passed a bill on FDA reform. It mainly focuses on drugs and devices. I mean, it is a big thick thing and 95 percent of it is drugs and devices. I won't get into that, in part because I don't understand all of it, it is very complex.

A part of that package, though, was the reauthorization of the Prescription Drug User Fee Act, which is the act that the drug side of the House has been operating under for the last five years, which is a user-fee based system for petitions or applications for new drug approvals.

In fact, the driving force for the timing of all of this activity is that the "PDUFA," as it is called, expires at the end of this month. Of course, the folks on the drug side of the House they have hired, I think, some 300 people to do that additional work, and those people are very nervous about whether or not they have a job on October 1 or not.

Actually, the House Budget Conference Committee last week did grant a one year extension to PDUFA, pending this legislative debate on FDA reform, which many people, at least on the Hill, thought that was a good vehicle, the PDUFA reauthorization was a good vehicle for broader FDA reform. I will talk a little bit more about the foods provisions in a minute, because there is a lot of similarity between what is happening in the House and the Senate.

At any rate, the Senate has acted; they are done. On the House side, they went for a long period of time without much activity. Last week, the subcommittee passed a bill. Yesterday, the full Commerce Committee of the House of Representatives passed, actually, two bills, one relating to drugs, which again reauthorizes PDUFA, the other relating to foods.

They are, this morning as we speak, taking up a third bill on medical devices. Again, the difference between what the House and Senate are doing, the Senate had all in one piece of legislation, the House has it divvied up into three separate parts.

Let me describe what is in these pieces. Again, the House, the full House, will take up FDA reform probably next week, either at the end of the week or the following week, because there are differences between what is in the Senate and what appears to be coming out of the House. There will have to be a conference committee to reconcile those differences before the two Houses take final action. Then, of course, after that it would go to the president.

There is still the potential that depending on how certain of the issues are resolved that the president could veto the bill if it contains certain things, and these really relate to drug and device issues, not foods.

Let me speak from having given you just that sort of general view of the state of play, to tell you a little bit about what is in the House bill. One of the issues that both Houses have been considering and both have a provision now dealing with is the health claims amendment to the

provisions that are now in our law that were put there by the Nutrition Labeling and Education Act of 1990. That law basically has provided, now for the last several years, that you could petition the agency to get a health claim approved for food label.

What these amendments, in both the House and Senate, do is say that if there is another body of government, the NIH or some other body that has taken a position on a nutrient health relationship, that is entitled, in effect, to a fast track.

The provision that is in the Senate bill and for that matter the one that is in the House bill did grow out of some negotiation. Although it puts pressure on us from a resource standpoint, it is a provision that we have basically agreed to. The House added a similar provision for nutrient content claims which we see as being largely a nuisance.

We don't think it marks the same level of priority. It is not in the Senate bill. The House, at least the Commerce Committee did approve of it yesterday for the House bill. It would provide a similar fast track mechanism for nutrient content claims.

The current law provides for, in every case, front panel referral statements to the back panel nutrition labeling. The House bill has a provision that would eliminate that in many instances, based on the theory that most people know to look on the back panel. We don't have any problem with that.

Another provision added, that is in the House bill that is not in the Senate bill is a requirement that we de-emphasize the irradiation statement that is currently required on all food products that have been irradiated. Basically, the provision says that the irradiation statement cannot be made any more prominent than the ingredient statement.

Another provision that relates to irradiation, we do have a petition pending before our Office of Premarket Approval that would deal with the irradiation of beef. The House has included an amendment that would require the agency to make a decision within 60 days after passage of the act or explain to Congress why not.

The law has long had it in a special provision, going back to the 1930s, that grew out of the fights between the dairy industry and manufacturers of margarine. Most of the provisions of that bill are being stripped out, of that part of the law are being stripped out, of another House amendment. It is of no real consequence to FDA, but it is obviously important to the affected industries.

Yesterday, two additional things were added to this. The FDA reform has gotten to be sort of like a Christmas tree and everything is hung on it. One of the ornaments that was added yesterday in the House was one that said that FDA could not take action again lead decoration, on glasses for one year.

This grows out of some situations earlier this year where we took some action against some highly decorated glasses with cartoon characters, using leaded decorations. These glasses were aimed at kids and some of the decorations got up in the lip and rim area, and both we and the Consumer Product Safety Commission have long had concerns about lead, particularly in the lip and rim area and particularly for kids. We took some regulatory action.

Also, as a part of that, we decided it was time to terminate a voluntary agreement that we, FDA, CPSE, and EPA, had with the decorating industry going back to 1979. I mean, that was a big improvement at the time, but we decided that today based on current knowledge about lead that the voluntary program was not sufficiently stringent, and so we have terminated it. We announced our intention to terminate it.

The glassware industry is very concerned about the next shoe, which will be the issuance

by FDA of guidance documents that basically say absolutely stay out of the lip and rim area with any kind of lead decoration. They are worried about all of the glasses that have already been decorated, and so this bill, put forward by Congressman Clink, is to keep FDA from making this new document effective for one year. That is one of the Christmas tree ornaments.

The other thing that was added yesterday was a provision to shift from a petition review process for food packaging. We now review food packaging and other food contact surfaces as food additives because of the migration from plastics and other materials into food. We regulate, have always, or at least have since 1958, have regulated those as food additives.

A new provision is being put forward to go to a premarket notification system for food packaging. The Senate has a bill that basically grows out of negotiation between FDA and the industry that simplifies the system. It does go to premarket notification, but allows FDA to, nonetheless, take action should we discover at a later date that there is a problem with the migrants. It also allows us to, by regulation, establish that certain things have to go through the premarket approval process anyway, if we think up front that they raise public health issues.

With the Senate bill, we also get a user fee, not a large one, but a small user fee to cover the cost of the premarket notification system. The House yesterday put forward similar legislation but without the user fee. We are concerned about that because we think once this becomes law, we will get a flood of notifications, and it will have the effect of taking resources away from the direct food additive process, which is exactly the opposite of what we were trying to do.

With the user fee to cover premarket notification, we felt that we could take all of existing resources in the Office of Premarket Approval and have them devoted to handling the large petitions on sweeteners, fake fats, {IOn}et {IOff} {IOn}cetera{IOff}. We have some hope that in the Conference Committee, when it finally gets to that place, that the user fee will be reinstated. But that remains to be seen.

Those are just rough overviews. Again, the House is not done yet, and even after it is done, because of differences, it will have to go to a Conference Committee, so it is going to be a while yet before we know what this final legislation is going to look like.

Let me now, if I may, switch gears and talk about the new presidential initiative that you may have read about in this morning's "Washington Post." This is brand new. Some of the details are still being worked out. But there are two fundamental notions in it: one is that there needs to be a greater focus on what happens on the farm, particularly in the area of fresh fruits and vegetables.

As many of you know, we have been having some problems recently. Everybody, I'm sure, has heard about the problem with cyclospora on Guatemalan raspberries. We have also, going back a year ago, a big problem in this country with apple juice with e coli 157-87 pathogens on produce that either remain on the produce and cause illness or get carried over into finished product is a growing concern.

The traditional focus, we will continue of course to use HACCP for processing. We are about to come out with a proposal on juice based on HACCP, requiring HACCP for that segment of the industry.

But we have also had a growing feeling that more needed to be done to articulate some guidelines and do some education to better assure that growers both in this country and abroad do a better job of shipping from the farm a produce that is less likely to be contaminated.

That is one aspect of this, and we are not at the place where we can actually do

regulations. I mean, it is a new area for us. What we are agreeing to do and actually being directed to do by the president, I think the directive will probably come down next week, is to develop some good agricultural practices, GNP type guidance for what happens on the farm and including probably transportation.

It is part of, again, the larger "farm to fork" notion. You have to have something at all parts of the spectrum if you are going to assure adequate public protection.

Again, these guidelines will be directed both at domestic producers and foreign producers as well. That is the other part of what is happening here is an increased focus on imports, particularly fresh fruits and vegetables, a large and growing percentage of the fruits and vegetables we eat are shipped into this country from abroad. We need to get a better handle on that.

The other thrust of the initiative is to give FDA some very much needed new legislative authority in dealing with imports. Right now, we basically are limited to try to look at the food at the point of entry and then try and judge whether that food is contaminated or not, to put it in simplest terms.

As the number of imports have grown, our ability to look at import shipments has diminished. Even though we put a higher percentage in the imports today than we have in the past, our resources only allow us to look at a percent or so of imported product, depending on where it comes from sometime 2 or 3 percent. But most of it comes in without anyone looking at it.

The other problem, I guess, was manifested most clearly by the recent problem we had with the cyclospora. You know, looking at problems at point of entry is always difficult. It is more difficult if you are not sure what to look for, and still more difficult yet even if you know what to look for if you don't have adequate methodology to actually find the thing that you are worried about.

We still today do not have good methodology for finding cyclospora on berries. Now, we can find it in the stool of people who are sick, but we can't find it on the berries when they are coming in. So, there is a need for kind of a shift in focus from looking at the food at point of entry to looking at the system that produces the food in other parts of the world.

Under the World Trade Organization agreements, every country is entitled to insist that the food coming into its country provide the same level of protection that this country's system provides for. The importing country has the right to determine the level of protection that is appropriate for its citizens. As long as it is applying that level of protection evenhandedly to both domestic producers and foreign producers, it can adhere to that standard.

What we put forward and what the administration has accepted is the idea of actually building into our law the notion that if food comes from another country and it comes out of a system that does not provide the same level of protection that is provided in this country, then that alone is a reason to reject that import without us having to spend resources looking at each and every shipment.

This provision, as we have crafted it, provides for FDA to write regulations. We believe that it is general enough in the authority, that it gives us a great deal of flexibility to implement this in a sensible way if enacted.

For instance, some countries, Third World countries in particular, may have a lousy system in terms of protecting their own population, but some of them put together quite good systems to assure that their exports, on which many of them depend, meet the standards of the

country to which the exports are going.

We could recognize those kinds of situations if we are satisfied that they are adequate. I also believe that we have the flexibility under this provision to do something else. There may be situations where no system run by the government in some Third World countries is adequate; but private parties, some companies in those countries may, nonetheless, be capable of and willing to do whatever is necessary to assure that their exported food commodities do, in fact, fully meet U.S. standards.

Again, I think by regulation we could provide a mechanism, create a mechanism for recognizing those situations, again, where we are fully satisfied that the food coming to the U.S. fully meets U.S. standards. I think this would really significantly advance our ability to assure that the food that is coming to the U.S. is safe and to get that assurance long before the food arrives at our borders. I think that will be a big plus.

We believe that it is fully consistent with our trade agreements. We also think, or at least I believe, that it will greatly enhance this government and this agency's ability to get people to pay attention to us when we sit down to negotiate or otherwise engage in setting standards, whether we are talking about FDA's participation in CODEX and the international setting activities that they engage in.

Whether we are in a bilateral negotiation with another country around a mutual recognition of systems, I think our ability to assure that people pay attention to what we say will be enhanced by the existence of this authority. In fact, over the long haul I think the existence of authority will probably mean more in terms of our ability to negotiate and get people to pay attention to us than in terms of a practical enforcement mechanism.

With that I will quit. I will be willing to take questions for a few minutes. Again, understand that details are a bit up in the air both on the legislative front and this new initiative, but I will do what I can.

CHAIRMAN BRANDT: Any questions or comments from anybody on the committee?

Oh, sorry. Dr. Harlander?

DR. HARLANDER: Sue Harlander. If, for example, there are no tests right now that you feel comfortable with that would detect cyclospora, then I'm assuming this bill would give FDA authority to look at just production systems and assume that that would decrease the incidence of cyclospora, for example, in the absence of a test that we could require producers in foreign countries to comply with?

MR. LAKE: Yes. Part of the notion here, for instance, a lot of this ends up being common sense. If you go to this other place and you see that we are using sewage water, untreated sewage water, on their crops then that is probably not such a good idea. It is really things like that, and also including personal sanitation practices of workers.

I mean, as much as anything, what we are really trying to do is get some basic sanitation, good common sense ideas communicated down to the farmer/farm worker level not only in this country, which generally does pretty well, but more so in other countries where in many cases it is not done so well.

CHAIRMAN BRANDT: Dr. Benedict?

DR. BENEDICT: Steve Benedict. Considering that the FDA is underfueled by resource as we speak, how will these bills provide you guys with the ability to do all this observation on foreign shores?

MR. LAKE: Well, you know, there is no money in the FDA reform. We were hoping, in

fact still hope to get a little user fee around that. That is one issue for the whole agency, except as I said the PDUFA will be reauthorized for drugs.

Overall, the FDA reform is going to put pressure on resources. This new initiative is also going to put pressure on resources. It looks like we are not going to be able to get any money for 1998, fiscal 1998. Our budget is really past. The New Year starts next week, and it just does not look like there is any possibility for this fiscal year, upcoming fiscal year.

However, we have been assured that for the 1999 budget that this will be given priority. What we are trying to do is structure some things that we are capable of doing this year, and with the idea that we will get additional resources the following year in particular to be able to have more people actually go to other countries and in an intensive way examine what is going on in those countries. But again, a lot of that effort is going to be delayed simply because we don't have the resources.

Now, I should also say that the directive is also going to be addressed to EPA and USDA to give us assistance to the extent they can in the activity this year. I might say that part of it, too, and I should have mentioned this earlier, you know, the Agricultural Research Service does a lot of research, has a lot of money for research already.

The president is directing them to shift their priorities, to put research dollars into areas that will answer some of the questions that need to be answered to deal with problems of pathogens on fresh produce, also to help get more information on what exactly should people be doing at the grower level to lessen the likelihood of the pathogens getting there in the first place.

CHAIRMAN BRANDT: Other questions or comments?

Thank you very much for coming.

MR. LAKE: All right. Thank you.

CHAIRMAN BRANDT: We appreciate being brought up to date on everything including this morning's "Washington Post," which is pretty nice.

Any other comments by anyone in the room?

Well, we are hereby adjourned, but remember the two working groups are going to meet. I don't have the foggiest idea where. Somebody will make arrangements. Have a safe trip, and look forward to seeing you in November to discuss an unknown topic at an unknown spot.

(Whereupon, at 9:55 a.m., the FOOD ADVISORY COMMITTEE MEETING was adjourned.)

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