

vsm

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

**NATIONAL ADVISORY COMMITTEE**  
**ON**  
**MICROBIOLOGICAL CRITERIA FOR FOODS**  
**VOLUME II**

Wednesday, September 22, 1999

8:10 a.m.

The Washington Room  
The Washington Plaza Hotel  
Ten Thomas Circle, NW  
Washington, D.C. 20005

MILLER REPORTING COMPANY, INC.  
507 C Street, N.E.  
Washington, D.C. 20002  
(202) 546-6666

P A R T I C I P A N T S

AGENCY REPRESENTATIVES:

I. Kaye Wachsmuth, Chair  
Morris E. Potter, MD, Vice Chair  
Arthur P. Liang, MD, MPH, Centers for Disease Control  
LeeAnne Jackson, FDA  
E. Spencer Garrett, Commerce Department  
LTC Scott Severin, Defense Department

Dr. Karen Hulebak, Executive Secretariat  
Jacque Knight, Advisory Committee Specialist

ADVISORY COMMITTEE MEMBERS:

David W.K. Acheson  
James D. Anders  
Dane T. Bernard  
Robert L. Buchanan  
James S. Dickson  
Catherine W. Donnelly  
Stephanie Doores  
Michael P. Doyle  
Mel W. Eklund  
Daniel L. Engeljohn, PhD  
Jeff A. Farrar  
Michael G. Groves  
Michael L. Jahncke  
John M. Kobayashi  
John E. Kvenberg  
Earl G. Long  
Roberta A. Morales, DVM, PhD  
Nancy E. Nagle  
Marguerite A. Neill  
Alison D. O'Brien  
Michael C. Robach  
Angela D. Ruple  
Skip Seward, II  
William H. Sperber  
William H. Sveum  
Balasubramanian Swaminathan, PhD  
Katherine M.J. Swanson

C O N T E N T S

PAGE

**Update on Performance Criteria for  
Fresh Juice**

Dr. Morris E. Potter, FDA 4

**NACMCF Bare-Hand Contact Discussions Continued** 8

Committee Recommendations 79

P R O C E E D I N G S

[Off the record discussion.]

CHAIRPERSON WACHSMUTH: We talked a little bit before we started this rambling that Morrie could get into the opening of the juice issue. He's got a short two-pager and we'll just bump that up from after lunch.

**UPDATE ON PERFORMANCE CRITERIA FOR FRESH JUICE**

DR. POTTER: This is the 1:30 slot on your schedule for this afternoon. All we want to do today on juice is introduce the topic. We aren't really prepared to discuss it, but we want to let you know why we're calling the meeting on December 9 and 10. So I've got two pages. I was going to read the charge on bare-food contact again because I enjoyed it so much yesterday, but LeeAnne did not enjoy it yesterday and has made copies and passed it out. So I think to substitute for that pleasure, I'm going to read this two pages on juice.

After the October 1996 apple juice outbreak from E. coli 0157:H7, FDA held a public meeting on juice safety on December 16 and 17 of 1996. The Fresh Produce Subcommittee of NACMCF attended the public meeting, met afterwards, and then made recommendations to the full committee.

Based on the information that was presented at the meeting and on the subcommittee's expertise, the full advisory committee made several recommendations. NACMCF concluded that the history of public health problems associated with fresh juices indicated a need for active safety interventions; and (2) for some fruits, for example, oranges, the need for intervention may be limited to surface treatment, but for others, additional interventions may be required, for example, thermal pasteurization.

NACMCF recommended to FDA the use of safety performance criteria instead of mandating the use of a specific intervention technology, for example, thermal processing. The committee suggested that an adequate level of safety may be achieved by requiring interventions that have been validated to achieve a cumulative 5 log reduction in the target pathogen. In addition, the committee stated that HACCP and safety performance criteria should form the general conceptual framework to ensure the safety of juices and that control measures should be based on a thorough hazard analysis.

In the Federal Register of April 24, 1998, FDA proposed to adopt regulations to ensure the safe and sanitary processing of fruit and vegetable juices. In the proposed HACCP rule, FDA tentatively concluded that a

preventive system, such as HACCP, appears to offer the most effective way to control the significant microbial hazards along with other hazards that represent juice-associated health problems.

In addition, in the Federal Register of July 8, 1998, FDA published a final rule requiring that juice products not specifically processed to destroy harmful bacteria bear a warning statement informing consumers of the potential risk of foodborne illness associated with the product.

To avoid the warning statement, juice manufacturers must process juice in a manner that will achieve a 5-log reduction in the most resistant pathogen of public health concern.

However, citrus juice processors who applied for an extension were allowed additional time before the labeling requirement became effective to develop and validate intervention measures that achieve the 5-log pathogen reduction standard. The 5-log reduction performance standard that the NACMCF recommended also has been tentatively included in the proposed HACCP rule as a mandatory component of valid HACCP systems.

Comments received to the juice HACCP proposal and some recent FDA research on citrus fruits have raised

several questions about the performance standard and the most appropriate application for public health protection. Research also raised questions about the adequacy of surface interventions to meet the performance standard for citrus.

To address these issues, FDA is holding a public meeting on December 9 to which NACMCF is invited, followed by a meeting of NACMCF on December 10 to consider the new information. On December 9, FDA and industry will present research relevant to meeting the performance standard and parties concerned with current interpretations of juice safety data will offer alternative interpretations.

On December 10, FDA will ask the NACMCF to consider specific questions about the performance standard and then make recommendations to the agency. The agency will provide the committee with the questions and some relevant background information one month prior to the December meeting. Please plan to attend the meeting. The agency will be relying on the expertise of this committee to bring the juice HACCP rulemaking process to a conclusion.

Are there questions about what we intend to do or what we perceive the appropriate role for the committee in this? Dane, you look--

MR. BERNARD: Well, obviously, you're going to formulate some questions ahead of time.

DR. POTTER: Right.

MR. BERNARD: You just told us that we're going to have the meeting and we're going to discuss a number of things, but we don't know the questions yet and you're not ready to give us questions. And you're going to be [inaudible].

DR. POTTER: Well, actually I may be in the audience throwing rocks.

[Laughter.]

DR. POTTER: No basic questions on this? Mel?

MR. EKLUND: The document you were just reading from, are you going to make that available to us?

DR. POTTER: We certainly can.

CHAIRPERSON WACHSMUTH: Yes, that will be attached. We don't have a recorder. That will be attached to the minutes for the record.

DR. POTTER: Part of the reason for doing that now is while things aren't being exactly recorded, because it's written, it can be just slotted in.

CHAIRPERSON WACHSMUTH: Let's freshen our coffee and give it another ten minutes. We'll just skip our morning break.

[Whereupon, a short break was taken.]

**NACMCF BARE-HAND CONTACT DISCUSSIONS CONTINUED**

CHAIRPERSON WACHSMUTH: Okay. We're powered. Everything is working. It's time for the committee to work.

DR. POTTER: Okay. Our systems are up. We're ready to go. Good morning once more. I hope everyone has their blood caffeine level up to an appropriate level insofar as there's enough caffeine in the world to sustain you through this morning's session. We'd like to get started on the question of bare-hand contact so that the agencies can start getting your feedback.

The first question before the committee is an appreciation of your perceptions on bare-hand contact with ready-to-eat foods as a contributing factor in the transmission of foodborne disease. So I'd like to open there and get a sense from the committee of your sentiments on that issue. Surely someone has an opinion. David.

DR. ACHESON: Well, for what it's worth, I think unquestionably from what we heard yesterday, certainly in terms of sick food workers, there's clearly a link between sick food workers and transmission through bare-hand contact into food and then on to people with regard to outbreaks. But that's stating the obvious, but it's just to get the ball rolling.

DR. POTTER: Katy.

DR. SWANSON: I'd like to build on that. In and of itself, bare-hand contact does not contribute to disease. It's the sick individuals who handle food that contribute to disease.

DR. POTTER: John.

DR. KOBAYASHI: I guess my answers to your questions are yes, yes, and a combination of all of those.

[Laughter.]

DR. KOBAYASHI: I guess in my mind, it's difficult to separate out or to choose as the question is stated, please signify which of the following is most important in terms of infected workers handling food, handwashing regimens and then no bare-hand contact. I think that those aren't really mutually exclusive events and I think common sense would argue that it has to be all of those in some sort of combination. The question is what is the appropriate combination?

One general comment I have is that while there are many, many articles about foodborne disease and infected food workers and contact with food as the mode of contamination, a question is is if there is a particular role of some sort about bare-hand contact or handwashing or whatever, what is the overall impact on foodborne disease? And from what I know, that data is pretty hard to come by.

Back in the '80s, we did a small study in the Seattle area where we looked at restaurant inspection records in restaurants in the Seattle area and compared that with the occurrence of foodborne disease in about a year and a half's period of time. And fortunately in that area, the restaurant inspection records were computerized and that allowed us to identify about 24 foodborne outbreaks which occurred in that area related to restaurants and identify the inspection records which inspections occurred before the outbreak occurred.

And we compared that with a set of unaffected restaurants in the same area that were inspected at the same time and compared what the inspection results were. Not surprising or perhaps surprisingly, things that we thought were important were important with regard to risks of foodborne disease. And, in particular, presence of adequate handwashing facilities was important and if they were not there, the risk of foodborne disease was several-fold over the baseline for restaurants.

The interesting thing was at that time, to my knowledge, there was only one other study in the literature which had done the same thing and that was cruise ship inspections performed by the CDC. Nobody else had done that even though the critical item method of inspecting

restaurants has been around for some time and is used nationwide.

I would think that the best way to determine the effect of bare-hands contact would be to do some similar study like that. I think that any--it's not difficult to come up with anecdotes or particular outbreaks on how contaminated food workers can infect many, many people, but the question is if we have a national policy with regards to bare-hand contact or whatever, what is the overall effect of foodborne disease and what is the cost of having that requirement?

DR. POTTER: Mike Robach.

DR. ROBACH: I'd like to agree with Katy and David on the issue with ill workers. I think that in and of itself is a separate situation and it needs to be addressed and otherwise I think the issue again is one of food contact surface sanitation, regardless if it's hands, gloves, utensils, countertops or boards, and I think that's the approach that we need to take in looking at the information, and I think Dr. Wong's data yesterday demonstrated that if you have contaminated hands or contaminated gloves, you're not in a good situation either way.

So the key there is to make sure that you've got adequate facilities and procedures in place to assure that

whatever is coming into contact with the food is adequately cleaned and sanitized.

DR. POTTER: Alison.

DR. O'BRIEN: What I heard yesterday--maybe Dr. Kobayashi heard something else--was that in New York, there were data that said if you enforce bare-hands, a prohibition on bare-hands contact, you did have an effect on foodborne illness within restaurants. And I also heard that in Massachusetts, although there were no overriding state guidelines that they had enforced such a policy in some situation and it had a similar effect.

To me those data say that no matter what the reasons, that the ultimate objective is to reduce the incidence of disease associated with retail business and if you prohibit bare-hands contact, at least in this small study, and although New York state is not small, there seemed to be an effect. And for me, that overrides all the other issues we're talking about. Those are the only data I've heard that really are convincing one way or the other that there is an effect to the ruling that FDA has presently. So I would actually go for point three on this discussion: that is bare-hands contact is prohibited, period, however you work at that. I'm not necessarily pro-

gloves. There are other ways to do this, but, you know, if gloves are what's needed, so be it.

DR. POTTER: Katy.

DR. SWANSON: I think one has to be careful with looking at the New York data. Yes, it was apparent from the data that we saw that the incidence of disease did drop after the implementation of that rule. However, we don't know why. One would suspect that when you implement a rule like that, there's a tremendous educational effort that's going on about why this is being implemented, and it just might be that in the face of that, they don't want bare-hand contact because people carry disease which makes people more aware of keeping the ill workers out, makes people more aware of washing their hands, make people aware of minimizing bare-hand contact.

So to make the leap that it was only the bare-hand contact that delivered that result I think would possibly be a mistake.

DR. POTTER: Okay. We have four placards up. Alison, did you have--

DR. O'BRIEN: I didn't say that. I said whatever the reason that resulted in--they instituted a policy and then the policy apparently had an effect. I didn't say what the reason was. It could have been education. It could

have been better awareness. It could have been anything, but it did have an impact.

DR. POTTER: Okay. We have six placards up right now and we'll get to each, but remember the question was for ill food workers, well food workers with sick family members, and well food workers whose hands were dirty because they touched a contaminated surface. So while this is valuable information on ill food workers, we will at some point need to expand the discussion.

Art Liang.

DR. LIANG: My point was already made.

DR. POTTER: Okay. Thanks. Dane.

MR. BERNARD: Thank you. Dane Bernard. I do think it's a valuable point to keep in mind the comment regarding workers with gloved hands and without gloved hands, that the microflora at least in well workers after some exposure to the environment is virtually the same whether it's gloved or non-gloved. So in terms of the potential for spread of illness, it kind of comes back to ill workers and whether we can dependably enforce hand-washing policies or whether we need to go beyond that is kind of really the context of the question for me.

I was very interested, as we had the presentation yesterday and the New York data as well, we did show

according to the slide that's on page ten in the handout, once the policy was instituted, there does appear to be a lowering in the overall outbreaks. However, the proportion of the outbreaks related to hand contact remains virtually the same.

So I find it difficult to draw any concrete conclusion from that data, although as Jack Guzewich said yesterday, if you look at the hepatitis outbreaks, they didn't see any where the no bare-hand contact policy was enforced. Now that's hardly what you would call a definitive study, but it does have at least some relative meanings. So I think those are pieces of information that we need to keep in mind.

The other thing, Mr. Chairman, I wanted to ask is going back to the original charge to the committee. As we are supposed to be providing comment to be taken forward to the National Advisory--to the National Conference for Food Protection on the science, I believe, where do we cross the line into policy and how far afield do you want us to go in that area?

DR. POTTER: To directly respond to the last point, we would prefer keeping this very tightly focused on the science as you understand it, and the risk management decisions the agency arrives at based on your

recommendations will then make that transition from the science into policy. Bear in mind too that the bare-hands was, as was reinforced yesterday, not a glove issue but any kind of barrier. Dan Engeljohn.

DR. ENGELJOHN: Yes, this is Dan Engeljohn. There were a few points that I have questions in my mind related to if we have enough information. And that would be in terms of the scope, do we need to distinguish between various types of ready-to-eat foods? The characteristics of those foods, whether or not they're wet or dry at the surface, the type of contact, whether or not there needs to be rubbing or just touching or some type of friction, and then the last issue would be do we have information, sufficient information, on the hands themselves, whether or not they're dry or the gloved hand is dry or wet? And so those are the questions I have remaining in my mind on the issue.

DR. POTTER: Okay. Thanks, Dan. John, has your issue been taken care of? Okay. Skip.

DR. SEWARD: Well, Dane really brought up the point that I wanted to make about the New York state data, but to me the questions based on the science are pretty straightforward in that I don't think there's any question that, you know, hand contact with ready-to-eat foods is a

contributing factor. I think the science says that it can be under certain circumstances. Can the transmission be interrupted? Yes, it can be through certain interventions and I think the science says that if you keep ill workers away from the workplace or away from handling food that that will be taken care of and it will help reduce the incidence of foodborne disease.

And certainly if you wash your hands, that will reduce it. I think the science--we saw that handwashing does prevent that. The last part is the part where I feel the science isn't really adequate to say that you're going to get maximum protection by having a blanket no bare-hand contact with ready-to-eat foods type of regulation. I don't think there is sufficient science to say that that's going to happen.

DR. POTTER: Thanks, Skip. Mike.

DR. JAHNCKE: Mike Jahncke. I found it interesting the data that was presented yesterday. They indicated some data with outbreaks associated with no workers involved versus with workers involved. And it's sort of like two sides of the same coin. When no workers were involved, 53 percent of the outbreaks were associated with bacteria and less than 30 percent with viruses. And some of that can be attributed to poor heating and cooling

of the product, poor sanitation. These are issues that in the food industry, we deal with all the time.

On the other hand, on the other side of the coin, when workers were involved, it was 53 percent of the outbreaks associated with viruses and 30 percent with bacterial. The wild card in it goes back to supporting what Mike was saying are the ill workers and that's a whole different area of how to identify and exclude ill workers from handling ready-to-eat products or handling food products in general. There are intervention methods that have been successful, as I said, in the food industry as far as heating and cooling products and proper sanitation, cleaning food contact surfaces and things like this, good manufacturing practices, SSOPs and these types of things.

But I think, supporting what Mike was saying, it does come down a lot to good sanitation of food contact surfaces and the wild card is how do we go about or how do the agencies go about excluding ill workers?

DR. POTTER: Okay. Thanks, Mike. Bob Buchanan.

DR. BUCHANAN: Morrie, I'd just like to recapitulate what I thought were the four questions that came out of yesterday's discussion and then just look at the data that was derived from it. The first question was what is the role of ill workers as a source of pathogens in foods

and its association with disease? I felt that the epidemiology certainly made a very strong case that ill workers played a major role.

Second question is really one question divided up into three segments. They are effectiveness of bare-hand contact prohibition to prevent the transmission of pathogenic organisms of fecal origin from infected food workers. The second is the effectiveness of the prohibition to prevent transmission of pathogenic organisms from non-intestinal sights. And third, the effectiveness of the bare-hand contact to prevent transmission of pathogenic organisms from raw foods or the environment to ready-to-eat foods. Those were the four key questions I saw.

In terms of the bare-hand contact prohibition, we were only provided data on one potential intervention. That was gloves. We have, as far as I can tell, no other data presented or information available concerning the efficacy of other interventions like utensils or whatever. So it's going--as far as I'm concerned--virtually impossible for us to look at the science with no data at all for anything other than gloves.

Going back to what I heard from the gloves in terms of presentation of data, there was a variety of experimental and sort of word-of-mouth anecdotal data

related to the efficacy of gloves for preventing the transmission of disease organisms from an infected worker who has an infection with an intestinal site of origin.

I saw a minimal amount of data presented for its role in pathogenic organisms from non-intestinal sites and almost all of that was limited to staph aureus. I heard essentially no data at all on the role of gloves in preventing transmission from raw food or the environment to the ready-to-eat food, and I would be very hard-pressed to come up with anything other than a theoretical consideration for that last question.

So I think right now if I was going to pick any of these, the only one that I see--we have certainly data on the role of ill workers. We have some data on the use of gloves to prevent these ill workers from transmitting disease to the food. I don't think we have data that's been presented to us in any form to deal with the last two questions.

DR. POTTER: Thanks, Bob. Skip, does that pretty well correlate with your comment as well?

DR. SEWARD: Right.

DR. POTTER: Okay. Cathy Donnelly.

DR. DONNELLY: There's another component of this issue that might strengthen the perspective of where we're

trying to get on this issue and that's protecting healthy workers from being contaminated by contaminated foods and I just think of an outbreak that was reported in MMWR on Salmonella enteritidis that in eggs has been classified as an occupational hazard for workers.

And I'm just wondering whether bringing that component into the argument of bare-hand contact might be useful to provide some perspective because right now we're focused in this argument on the ill workers, but aren't we trying to achieve overall public health protection? And I would feel that protecting the workforce that are on the line in contact with these foods is going to bring some balance perspective to this perhaps.

DR. POTTER: Perhaps using the analogy of protecting health care workers from patients.

DR. DONNELLY: Exactly.

DR. POTTER: Okay. Thanks. Nancy.

DR. NAGLE: Thank you. I think some of what Bob said kind of already got to where I was getting with this, but, you know, I think if we look at the questions that you've asked here, it's really difficult to say that we have enough data to answer question number three, subpart three in there. I just don't think we have enough information to make that blanket decision there, and I think there was

enough evidence presented that said there's still questions out there about gloves or about some of these other utensils that we need more data generated, especially on the things that are not gloves, because we heard about handles and that food contact surfaces need to be separate from the part that the worker handles, and I think, you know, that that's really a critical issue and we don't have enough data on that. And to try to make this decision or to make this a blanket, yeah, no bare-hand contact, I think would be premature.

DR. POTTER: Dr. Swaminathan.

DR. SWAMINATHAN: The way I approach problems is to take an aerial snapshot of it and then move down and look at the details. What I heard yesterday told me that hands are an essential equipment for food processing and food preparation. Whether it's bare or gloved, hands are needed for making sandwiches, peeling shrimps, for--okay--and other examples such as the ones enacted by our chair.

If you look at hands then as essential equipment, obviously as you require for any other food contact equipment, they ought to be in such a condition that they don't contaminate the food, broadly speaking. There are two critical control points as far as meeting that requirement

is concerned. One is who or what the hand is attached to. An ill worker comes in here.

And the second one is where the hand has been before it contacted the food. Those are the two elements that broadly color everything related to this bare-hands question that we are addressing.

In terms of interventions, I agree with Bob Buchanan and John Kobayashi and several others that we have not heard any conclusive evidence that one technology or the other is superior other than handwashing, and that also, I think one important point that we should not forget is the simpler the better. We did not see any evidence that antimicrobial soaps were any better than just plain soap. We did not see any evidence that longer handwashing is better than a ten second or less, ten second handwashing.

One last thing that I would like people, one thing we should keep in mind is what Jack Guzewich mentioned yesterday in his presentation that it makes sense to have multiple barriers. One may not do, one may fail, but if you have multiple barriers, you have more protection. So let's look at it from a global standpoint and then narrow down and get closer to the problem and look at the details.

DR. POTTER: Okay. Thanks, Swami. Committee reaction to that? Dane.

MR. BERNARD: Thank you. I'd like to know what the chair had to add in terms of what hands are used for, but we can maybe cover that later. I have to agree with Swami and we can only go so far with the information that we were presented from a scientific standpoint and then you get into the opinion and the opinion about policy, and you've given us a charge to sort of stay away from policy, but I think that without a doubt I think we can say that bare-hand contact is to be avoided where possible, and gloves as a barrier can certainly, I think, enhance the prevention of transmission of certain diseases.

And again, here's the opinion, that based on some of the anecdotal comments during the presentations, that handwashing compliance is something that is certainly less than 100 percent, and depending on how good the management is in a particular establishment and how adequate the facilities are, it may be a lot less than that.

So I think that we can say that gloves as a common practice are probably a good thing, but I think we've also based on some of the presentations, my opinion is that there are certain operations where gloves are just not going to be able to be used routinely successfully.

I know that wanders a bit into the policy area, but I think that a blanket recommendation that says

absolutely no bare-hand contact is probably not a workable option but is the preferred standard operating procedure.

DR. POTTER: Jim.

DR. DICKSON: I'd like to take from what Dane said, I think the issue that we're all wrestling with is the difference between the theory and the practice. In theory, handwashing is good intervention. In theory, use of gloves is a good intervention. The question really is the practice. If people don't wash their hands, the best theory and the best scientific data really don't mean very much.

Likewise, with gloves, gloves are an excellent barrier method, but if people don't change them routinely, then the practice of that is not very good, and I think that's an issue that we may not be able to resolve strictly by scientific data because, as I say, the theory is one thing but the actual practice by the industry is something quite different.

DR. POTTER: Katy.

DR. SWANSON: May I suggest a potential process to help us get to an end product by the end of however much time we have here because to John's point early on, it's kind of a combination of factors. You can't consider each one of these in isolation, but perhaps if we try considering the prohibition of ill employees, the handwashing and go

around the room and talk about them one by one, identifying what the science has told us on each one of those topics, we can get to the end and have something that we can recommend to the Conference for Food Protection. Does that make sense?

DR. POTTER: That does indeed. It presupposes that the committee has reached consensus on the first two questions. That being that hands can transmit and that it is possible to interrupt transmission.

DR. SWANSON: Well, maybe we should start with the top questions then and just go through one by one.

DR. POTTER: Does anyone not agree with those first two? Okay. In that case, I think that based on your collective wisdom and the information presented yesterday, we can sort of say yes to those and move to the third set of questions. Roberta, you had your flag up.

DR. MORALES: Yes. I was actually going to say that I have to agree. I had the same problems that Jim has been wrestling with, you know. There are two issues here that I see is that one is we know what the science is and truly while there's evidence to support the three interventions, at the same time, the reality of the situation also comes in as far as whether or not that science is going to be effective. So I actually like the

suggestion of going around because I think that may get us to some resolution on this because all three provisions to me have merit.

I am not sure that any one of them will fulfil the objective of achieving the food safety level that we are after and so maybe in doing that, we might come to some consensus on what are the different combinations possibly that we might be able to approach.

DR. POTTER: Okay. All right. Well, let's follow up on Katy's comment then and start with the likely, the data to support a position on the likely level of public health protection from prohibition of ill food workers. Is that question stated appropriately first? Okay. Katy, do you want to start and we'll just work around the table?

DR. SWANSON: Okay. I personally think that that's the single-most effective method to interrupt transmission because when we've heard about the cases that did occur, most of them, many of them did involve sick individuals who are handling product. Also, it prevented not only transmission of the agent to the public, but the Minnesota data showed that it prevented transmission of the agents to other employees who would then become ill who would subsequently prolong the exposure to the public, but we also learned that that was not in and of itself

sufficient to prevent disease because there are asymptomatic carriers that exist and there are those who may be shedding organisms prior to the onset of symptoms.

So the science strongly supports that ill employees should not be tolerated in handling food product but again it isn't in and of itself sufficient to present transmission.

DR. POTTER: Okay. Thanks, Bill, did you want to pass on this round?

DR. SVEUM: I just walked back in from a page. I'm sorry.

DR. POTTER: All right. Swami.

DR. SWAMINATHAN: I think Katy has stated the facts to my liking. I don't have anything to add.

DR. POTTER: Okay. Bill.

DR. SPERBER: I certainly agree with the premise that prohibition of ill workers will reduce illness, but it's not very effective in practice. If I could just think ahead to the second part of this for a second: handwashing as an intervention is well recognized as an effective step and we can't get people to do that. I think we would be even less effective in prohibiting ill workers from handling foods.

Even if we could do it, it could not be effective because of the existence of asymptomatic carriers, because people can be incubating illnesses for a long time and be asymptomatic and still be handling foods and contaminating them, spreading illnesses. We have millions of people involved in this industry handling foods. They have an economic incentive to work when they're ill. They will try to mask their illness. We have hundreds of thousands of supervisors who will be tasked with detecting ill workers and they will not reliably perform that task to keep ill workers from handling foods.

So I think from a scientific or academic sense, this statement using prohibition of ill workers as an intervention is a laudable goal, but I just don't see it working.

DR. POTTER: Skip.

DR. SEWARD: I agree with all the comments that have been made here so far. The only thing I would add is that if you do have a sick employee, then the requirement typically is that they have two negative stools before returning to work. And that's all I have to add really.

DR. POTTER: Okay. Angela.

DR. RUPLE: I also agree with the comments that have already been made. Obviously, prohibition of ill

workers can be effective, but there is definitely some question as to how that can be accomplished.

DR. POTTER: Mike.

DR. ROBACH: I think prohibiting ill workers from working in food preparation establishments is an excellent first step and I would go one step further, not only prohibiting them from preparing food, but from coming in contact with other food contact surfaces.

DR. POTTER: Peggy.

DR. NEILL: I agree with the comments thus far. I think the statement has to stand because the lack of such a statement is really unacceptable from a public health point of view. The caveat simply would be that the attendant reduction in transmission is on a pragmatic basis probably small because of the very pragmatic issues that arise for how you carry out this particular step. So I think it's sort of a done deal. You just say yes, but we don't really delude ourselves that it's going to have a very significant impact.

DR. POTTER: Nancy.

DR. NAGLE: Yeah, I pretty much agree with, you know, what Katy said and back on that, and I do think there is some issue of trying to execute against this. But again, let's--and we bring up the idea of all of the asymptomatic

workers, but still if we can accomplish the ones that are obviously sick and keep those out of there, we see a significant reduction in transmission from them because, you know, a good portion of the illnesses that were reported to us showed that they had actually sick workers. So I think there is some benefit to attempting to do that. Again, the execution will be a challenge.

DR. POTTER: Alison.

DR. O'BRIEN: Clearly I agree that keeping sick workers out would be a wonderful goal. I don't think it's practical nor do I think the retail business is ready to institute sick leave, universal sick leave, or things that may have a small impact on keeping the very sick worker out. It wouldn't have an impact on keeping someone that doesn't know they're infected out of the workplace. So it's theoretically a great idea, practically difficult to achieve with the current environment.

DR. POTTER: Roberta.

DR. MORALES: I also have to agree with all the statements that have been made. It is an important provision for public health and there is evidence that supports that there are going to be--there will be disease transmission from ill and infected workers. I wonder if maybe the functionality of the statement might be adjusted

by saying ill and known infected workers as a possibility because to me infected means--it brings up a whole plethora of the asymptomatic as opposed to symptomatic or known infected routes--and perhaps that may allow this provision to become somewhat functional in its implementation.

DR. POTTER: Earl.

DR. LONG: I cannot find any arguments against prohibition. Anything that I'm going to say has been said before, but recognize that there are limitations to the effectiveness of prohibiting ill workers from contact with food.

DR. POTTER: John.

DR. KVENBERG: Thank you, Chairman. I actually picked up the food code and began reading it in its latest version and I think one of the issues that the committee seems to be underscoring endorsing is the employee health section on diseased workers and would like to just merely point out that the food code actually puts the responsibility of the person in charge to require reporting of employees and applicants and it further gets into exclusions and restrictions of what these employees are doing, and I think the question at hand here is basically how do you provide the barrier for ready-to-eat foods being contacted by ill workers, and that's really not the main

question of the charge because we're talking about bare-hand contact and ready-to-eat foods.

So the point I guess is that I'd like to underscore that the food code does address restriction of employees, assessing medical conditions and limiting their functions and duties to where they're not exposed to ready-to-eat foods, and that provision really isn't one I think of major controversy for the Conference for Food Protection. So it's a minor issue.

DR. POTTER: Thank you. Okay. Bill.

DR. SVEUM: I would certainly agree with the statements that have been made in particular because there's evidence that infected workers have caused foodborne disease and really it's key here, and one of the first steps in the intervention to put a program together that you want to keep the infected workers out of the food place.

DR. POTTER: Okay. If I may summarize what I hear from this side of the table, perhaps we can come to closure on this question before we go on. I guess what I heard is that the committee is satisfied that the scientific evidence provided, the data that exists, document that ill food workers may contaminate food through bare-hand contact and that exclusion of ill food workers will interrupt transmission, but is not, will not be 100 percent effective

for a variety of reasons that have been detailed in the information. Nancy.

DR. NAGLE: You added a phrase there that I don't think we saw in the evidence. And you said that ill food workers can contaminate the food through bare-hand contact. We didn't see necessarily the evidence of that. They could have sneezed on it. They could have done other things as well.

CHAIRPERSON WACHSMUTH: What about the fellow who put his hand up to--

DR. NAGLE: Yeah, the guy, yeah. I mean we had those, but I think we want to make sure that it's not just bare-hand contact. There's other things they could be doing because talking about bare-hand contact didn't cover his elbow.

DR. SWANSON: And the literature did have examples of gloved employees who--

DR. NAGLE: Right.

DR. SWANSON: --transmitted disease.

DR. NAGLE: Right.

DR. POTTER: Okay. Jack, you're not part of the committee. Thanks. Control yourself.

[Laughter.]

DR. POTTER: Bob.

DR. BUCHANAN: Just to follow up a little what John said. For any of you that want to check the section out, it's pages 23 to 28 in the food code deal with employee health.

DR. POTTER: Okay. Yes, David.

DR. ACHESON: The only other question that could be brought up here is obviously the ill food worker without any doubt is a problem, but what about other family members? That really hasn't been discussed as to what we feel about that. You know if you've got a child with a clear presumptive infective gastroenteritis, I mean that to me is a risk. It's even harder to exclude that person perhaps.

DR. POTTER: And there were data to support or at least--yeah, information was presented to support the role of ill family members even if the food worker were him or herself uninfected. Is that?

DR. ACHESON: Yeah. I mean clearly that is even more impractical, but scientifically I think we've seen some evidence to support that it should be taken into consideration.

DR. POTTER: Okay. Any additional comments from this side of the table that have not already been made? Jeff?

DR. FARRAR: I guess I'm a little shocked that we're spending quite a bit of time debating the scientific merits of these first two subpoints. These are core values of public health. I don't understand why we can't move beyond those. Perhaps a minor tweaking of the wording is in order, but let's get beyond handwashing and excluding ill workers.

DR. POTTER: Okay. Now we did move very quickly through the first two questions and settled on the three parts of the third question. Is it the committee's sense that there is already agreement with the first two parts of the third question? That there are data to support these things that these should be at least somewhat effective although perhaps not effective to the exclusion of other practices?

Anybody disagree? Okay. In that case, we can move to the third part of question three: prohibition of bare-hand contact with ready-to-eat foods. That's principally where the discussion so far today has been. Perhaps we can start with David and work on this side of the table on summary statements for what information is known, what data exists as to the importance of bare-hand contact with ready-to-eat foods, and the likely public health merits of interrupting that.

DR. ACHESON: I think like everybody else I'm struggling with coming to a personal consensus on this one. The New York data that was presented yesterday was intriguing, but I wasn't convinced from what I saw that that drop was related to bare-hand contact, as already has been discussed. Clearly, just putting in a blanket prohibition is going to raise a lot of other questions and a lot of other issues. I mean if people are resorting to using these kinds of gloves, I would be concerned that bits of this is going to end up in my sandwich, you know.

I think it's very difficult to come to a sense to what this should be, but personally I'm not sure we've seen evidence to say that a blanket prohibition is where we should be going with this.

DR. POTTER: Okay.

DR. ANDERS: Well, I agree with most of what David said. I'm not sure that the evidence that we saw yesterday suggests that we necessarily should have a prohibition against bare-hand contact. However, I do have some concerns about--I think that just as there are problems with keeping an ill worker--and one of the statements was here previously, and hopefully that's going to be taken out of there--infected workers. I mean I don't know we can tell

somebody is infected and not symptomatic without doing a whole lot of testing before they come to work everyday.

So that is totally impractical. I'm not so sure here though that--I was concerned that primarily if a worker had an infection that there would be some protection, for instance, with gloves of that individual infecting food. I don't think there would be any question that there would be some protective barrier there if it were a good glove. Again, I agree that this glove would, I would not suggest would probably protect anyone. But I guess overall, I have a real problem with just saying that we should have a prohibition against bare-hand contact without any further evidence.

DR. POTTER: Dane.

MR. BERNARD: Thank you. As I said earlier, I found the report on the New York experience to be interesting but not conclusive. If we are limited to rendering opinions based on the science, I think that my analysis of that slim evidence would be that it speaks to no bare-hand contact as a good policy, but it's not yet conclusive.

Being a member of Council Three of the National Conference for Food Protection and knowing that I will see this topic again, I can't really stop myself from talking a

bit about policy which I did earlier. I think standard operating practice should be no bare-hand contact, recognizing that there may be instances or job tasks which may be candidates for variance.

I would encourage those who have that kind of specific knowledge to come up with a list of those kinds of tasks which would be candidates for variance because one of the problems right now is dealing at a local level with non-standardized practices that being variances from requirements in the code. Thank you.

DR. POTTER: Bob.

DR. BUCHANAN: Again, going back a little bit to my earlier breaking of the question down into multiple parts, I think the only thing that we have data on right now is infected workers. Having looked at the data provided on handwashing, while it is effective, it didn't appear to be completely effective. And I guess in the absence of any data, my inclination would be if we have a critical control point, that is washing of hands, and we know that it's not totally adequate, that if we can have a secondary barrier, be it gloves or utensils, et cetera, it seems to be reasonable to recommend that now.

I think we have to be a little careful here in ensuring that those are implemented, recommending

implementation in the manner that doesn't aggravate the problem, and that's going to get into the areas of behaviors, and while I understand we're here to deal with the scientific issues, as a scientist I have to look at human behavior, too.

And I have to be concerned about just rote implementation of these interventions. But I don't see any way around recommending in terms of what we know now that handwashing is not going to be totally effective and it would be a good conservative approach to recommend a secondary barrier.

DR. POTTER: Let me just see if I understand your comments, Bob, to see if, in fact, the first four comments we've heard are all consistent. You're basically saying that the information we have for ill food workers would suggest that we should exclude ill food workers, require people to wash hands to make up for those that don't get excluded, and then a secondary barrier to make up for the inadequacies of handwashing?

DR. BUCHANAN: Correct.

DR. POTTER: Okay. But only for the--the data only support that for the case of food workers ill with an enteric disease that can be transmitted through contamination of food?

DR. BUCHANAN: The data, what little was presented, did not seem to support that this would be an effective intervention at least in terms of hands for transmission of a pathogen from, for example, a raw meat to lettuce. That would not be, there was no data presented at all really and we fall back to theoretical and cross-contamination is cross-contamination.

DR. POTTER: Okay. Thanks, Bob. Jim.

DR. DICKSON: I have to agree with the comments that Dane and Bob made. I would take a little different approach to it, though. I think we would almost, almost invariably come to the conclusion that an avoidance of bare-hand contact is good policy. I suppose one of the things that intrigued me the most about yesterday was the lack of data supporting use of gloves during surgery. That doesn't mean if I go in for surgery tomorrow I would approve of my surgeon coming in and not wearing gloves even if the scientific data does not support that.

There may be specific operations that do not lend themselves to gloves or utensils. Those I would suspect are more limited than people in the industry would, in fact, suspect. But I think we have to come to a policy that recommends an avoidance of bare-hand contact under most if not all circumstances.

DR. POTTER: I think a few years back surgeons also rebelled at the idea of gloves because they lost some sensitivity. Cathy.

DR. DONNELLY: I agree with Jim. Where I come down scientifically is instead of the statement written here, a blanket prohibition against bare-hand contact, because I don't think the science is there to equivocally support that, but I think the avoidance where possible of bare-hand contact. I think there is scientifically compelling evidence to support that.

DR. DOORES: I think if you ask the general public how they feel about this situation, they would probably all agree that they would like their food handlers to wear gloves in those areas where they actually see food handlers handling food. They probably don't even think about it if it's back behind a room or in the kitchen or something like that where they don't see them handling. But these same people who buy food would probably rebel against the idea of the food handler handling coins with a gloved hand at the same time. They have that perception that that's sort of a no-no because you can get contamination.

So while I support the idea of using some kind of a barrier or no bare contact, I would also suggest that at some point--and perhaps it's not in this committee--that

clear definition has to be used as to how often, if the barrier is a glove, how often that needs to be changed or under what circumstances it needs to be changed. Or if you're using utensils, how often is that changed so that you don't have a prolonged use of either of these things and you're ending up with the same problem with no gloved hands.

DR. POTTER: Thanks, Stephanie. Mike.

DR. DOYLE: Well, I certainly agree with all that's been said. My biggest concern, though, is that I don't think we have enough data to support a blanket prohibition of bare-hand contact and we do really need a lot more data to support what should be done. And, you know, I said somewhat facetiously maybe the best approach is to use the gloves when you use the bathroom, but in reality, you know, that's the kind of research we need done, and it may be that that would be a practical approach to reducing the need to use gloved hands in food handling, but there's a lot more research that needs to be done. Even with handwashing, much of the data that we've seen and what the FDA is using for approvals is based on hospital infections.

And we can't always translate what goes on in the hospital when we're talking largely about nosocomial infections to real world of food handling. So I agree with what I've heard so far. But I think we need to get a lot

more data before we can make some hard decisions about making a blanket prohibition against bare-hand contact of foods.

DR. POTTER: It sounded like you were heading toward recommendation for no bare-hand contact with anything but food.

[Laughter.]

DR. DOYLE: You're trying to put words in my mouth.

DR. POTTER: Dan.

DR. ENGELJOHN: Yes. This is Dan. Just to touch on something that Cathy just said, that if we go in the direction of saying avoidance where possible, then that leads me to believe that there is some question that there may, in fact, be some products or some practices where there may, in fact, be the exception. And so I'm just, I still have that question in my mind as to have we fully addressed the issue that we're talking about all ready-to-eat foods without exception and all touching practices without exception? So it just leaves that in my mind as an area where I don't think we've answered that.

DR. POTTER: Dan, clarify for me, if you would, does this go back to Dane's point that if we, if the committee does not think that a blanket prohibition is

appropriate that the committee does feel that variances should be carefully specified and well characterized?

DR. ENGELJOHN: It goes to that, but I think it's important to note that it's for a science reason, not for impact or practicality reasons. I think that's where it needs to come out.

DR. POTTER: Okay. Mel.

MR. EKLUND: This is Mel Eklund. I agree with what's been said so far. I have visited many, many processing facilities over the years and I've seen people use bare hands and also people using gloves. And I have a comment that I usually make is that when people wear gloves, they become holier than thou. They can touch everything in the world, and things they've touched with gloves, they wouldn't even touch with their bare hands, and then go back to the food.

So I think it really comes back to what was emphasized yesterday in many different talks, and that's education and training. All of these things have to be put into place because you can use gloves, but I've seen people --management has to be involved, and if management does not have the right size gloves, I've seen people with big hands take their bare hands and try to push down the fingers so they can get their gloves on be in turn contaminated. So I

think it comes back to, a lot of it, to the education and training to put these things into place.

Definitely handwashing is an essential thing as we heard many times before. I mean it does not--gloves do not replace that. So adjustments have to be put into place and I think wherever possible that gloves should be used though because I think it does give you a second barrier and maybe a second chance to control things.

DR. POTTER: Thanks, Mel. Jeff.

DR. FARRAR: Clearly I think everyone I've heard so far agrees that the data are not there to support this. That's kind of a no-brainer as well, but I think we need to go beyond that. Our duty should also include discussions about what data needs to be provided, what studies need to be done, who needs to do those, what specific questions need to be answered. What is sufficient data for someone to conclude that bare-hand contact should be prohibited?

It's interesting, though, that in listening to everyone, I have the same inclination. Even after saying that the science isn't there, I'm inclined to comment on the policy immediately after that that we're not supposed to. But again, avoiding bare-hand contact seems intuitively appealing. It should be stated that way or similarly with variances spelled out.

DR. GROVES: Well, I agree with Jim that the avoidance of bare-hand contact as possible is good. I didn't hear anything that convinced me, however, that there was a cause and effect relationship between instituting gloves or no bare-hand contact in New York and the fact that there was a decrease in food transmitted diseases. So I really can't support a prohibition on bare-hand contact because I agree with also Mike that the data is not there yet to come to that conclusion.

Stephanie made a good point in that you feel real nice when the person making your sub like was making for my wife yesterday was using gloves, although I didn't feel quite as good when he picked up the pen and wrote the check out. But I also think that if my bartender was garnishing my manhattan with an orange and was wearing gloves, I might wonder what the heck he was carrying that I was going to get.

[Laughter.]

DR. GROVES: So I just don't think that at this point that I could support a complete ban on bare-hand contact.

DR. POTTER: Mike.

DR. JAHNCKE: After all, I have to agree with basically what everyone has said on this side. I would also

say that I think it's desirable to minimize the contact with ready-to-eat foods with bare hands, but placing a blanket prohibition on that I think is--the data isn't there and I think in practicality it's not there. Using gloves is one piece of the puzzle and by saying that you have to wear gloves in some ways it, as Mel was saying, comes down to training, implementation, all these at the plant level and at the retail level. So I would agree with Mike and the rest that avoid bare hand contact whenever possible, but a blanket prohibition I cannot support.

DR. POTTER: John.

DR. KOBAYASHI: I agree with what most everyone is saying. It's, I think, reasonable to say that bare-hand contact should be avoided whenever possible and so forth, but the main rub is whether or not there should be a rule which says bare-hand contact should be prohibited. With regards to the data, to a certain extent I think the data is not there. The New York data is interesting, but what I see lacking, and it's almost rather than the data not being there, maybe the data is there, but it hasn't been analyzed in the way it needs to be which is to say, okay, there was this program to prohibit bare-hand contact in New York state; what is the impact with regards to that program in terms of reducing foodborne disease?

And considering the amount of work involved to implement that program and considering the amount of reduction in foodborne disease, was it worth it? Is it something that should be done elsewhere? I think it would also be useful to have that type of question addressed in other parts of the country as well.

I think that one of the missing pieces that I saw from the New York data--I think it's there; I think it needs to be analyzed--is to compare what the practices are in a sample of restaurants or whatever that are not having outbreaks, and when you compare that with what is happening with the restaurants that are having outbreaks, then you can give some sort of measure as to the impact of that particular intervention.

DR. POTTER: Thanks, John. Anyone on this side of the table have things they want to share that have not already been said. Earl.

DR. LONG: Yesterday, some of the information we got pointed out the role of two groups of pathogens. There are the resident pathogens and the transient pathogens. Gloves, I believe, would provide adequate protection against the resident pathogens up to a point. The transient pathogens come from one source to the food. And I do not see how gloves would prevent that unless the gloves are

impregnated with some antibiotic. So gloves in themselves do not offer--offer only limited protection.

DR. POTTER: Okay. Any other comments? Nancy?

DR. NAGLE: Well, it was brought up slightly, but I think we really need to make sure that we keep in mind that the concern would be that this additional barrier, whatever it may be, may increase the risk of cross-contamination, and I think that is a real key. So we may reduce the ill worker transmission but increase the cross-contamination from raw materials or from pens, money, floors, anything else, and I think that data needs to be generated. What kind of practices happen or what kind of changes in the way people work happen when they wear gloves versus when they don't wear gloves and, you know, maybe that experiment that we talked about yesterday where one hand is in a glove and one hand is not, and let's see what's going on. We need more, there needs to be more data.

DR. POTTER: Okay. Nancy, Alison and John also wanted to comment, but let me understand something here because I didn't hear on this side of the table that there was a sense that there were data that suggested bare-hand contact was better than no bare-hand contact. And what I think I heard you say is that in some cases, barriers--

DR. NAGLE: Bob brought up--Bob suggested that be sure that you're not adding additional risk. And I think that is what he was getting at is that do the implements become contaminated and you continue to use, whereas you would wash your hands. And Mel brought that up as well. He said people touch things with gloves that they would never touch with their bare hands. So that's the implication that there is information out there that people may have different habits or practices when they're wearing a glove versus when they're not.

DR. POTTER: Okay. Alison.

DR. O'BRIEN: I'm going to continue to take the unpopular stand or at least it appears to be that we do need to continue to have such a requirement of no bare-hand contact. And it's not because I believe all the data are there, although I heard some, certainly the sick workers. It's because--just--I'm going to quote--make a quote here-- "As a scientist I have to look at human behavior." And because human behavior says that if you're sick, you have a sick child, and you're not getting paid to stay home, or you have to find somebody to replace you, and because human behavior says you're not going to walk outside your work area to go wash your hands if you're behind schedule, because of those issues, I think we need to have some

requirement in place that will overcome those problems. And whether the overcoming the problems is because gloves are really effective, I can't answer. We didn't hear that. But if what is happening is if there's a better education program, there's more awareness that somebody is looking over your shoulder, whatever the reasons, I think the little bit of data from New York were promising.

I will remind most of us that we didn't know for sure that safety belts were going to be helpful in cars, but they turned out to be, the requirement that we use safety belts. So I'm still going to take the position that I think even though it may not be scientifically justified, that I am in concurrence with point three.

DR. NAGLE: And if we waffle, the retail institutes will waffle along with us.

DR. POTTER: John.

DR. KVENBERG: Thank you. John Kvenberg. Just for the committee's benefit, what I've been struggling with personally is the actual wording of the code and the scientific advice that we can provide it. I am in sympathy with what Alison is saying because what is being asked for here, and if I be allowed to read it, it says except when-- the actual provision of the code, where it talks about the issue is is except when washing fruits and vegetables as

specified under another section of the code, or when otherwise approved, food employees may not contact exposed ready-to-eat foods.

The question is is where do you apply that and where is the science and what advice can you give to the person that must enforce a code, a law, a regulation? So where is the good science on providing guidance to those who are charged with inspecting the food service, I think, is the focus of this question? And what is the best advice we can give not only to the regulator but also the person who has to enforce it is the approval process and what is it we're trying to gain here and what are the limits and bounds and what is the science telling us on the issue of limiting the potential of exposure?

Frankly, the code talks about the fecal-oral transmission route. It's very clear in what it says. It's a limitation of human passage of either viral or bacterial pathogens of an enteric nature to the population. That's what this was provided for. So that's what I'm struggling with is what the committee can give us as far as science relative to what are the processes that are least risk, I guess, is what I'm asking? If bare-hand contact is essential in some places, what kind of guidance can we provide for bare-hand contact? Thank you.

DR. POTTER: I see a couple of placards up. Before we go to Dane and Bob, are there specific reactions to what John just read from the code? John Kobayashi.

DR. KOBAYASHI: I guess what I was hearing John Kvenberg say or ask is, okay, this is the wording of the food code. Does the committee have any advice on how that wording should be implemented? Should it be implemented aggressively or not aggressively in terms of whenever possible? I mean what does "whenever possible" mean? And I guess my comment is it appears to me that the evidence is growing that it should be implemented aggressively, that "whenever possible" means that, as opposed to avoid, don't worry about this, this is not an issue. Because I think there the data is there with regards to the New York situation where an entire state approached their food services with the no bare-hands contact and at least for New York, it appears to be working. And that's interesting.

And I think that common sense would argue that the less people contact food that's ready-to-eat with bare hands, the less likely they may transmit, and that life being the way it, is there are going to be people who are sick who are still going to work and so on and so on. So I think we're at that stage, but I don't think we're at the stage where we can say it should never be done.

DR. POTTER: Okay. Other specific reactions to John Kvenberg's comments from the code? Jeff?

DR. FARRAR: As it's written, I'm interpreting the term that's tagged on there, "whenever possible," to be guidance. It's damn difficult for regulators to enforce that term. So I agree with the term "whenever possible" as it's written, but on the other side of the coin, if we're expecting that to be enforced at the local level, it's going to be very difficult.

DR. POTTER: Let me follow up with a question to you, Jeff. You said earlier that we had an obligation to define what researchable questions needed to be answered. Are those researchable questions when barriers should be put in place or under which conditions variances do not pose a public health hazard?

DR. FARRAR: Those are certainly two that we need to define absolutely and I think there are others as well.

DR. POTTER: Okay. Specific to Kvenberg?

DR. ROBACH: Yes. Well, specific to the food code, two things. One, it says "or when otherwise approved" as opposed to, you know, "when it could be avoided." And the other thing that's interesting in the food code is it specifically talks about single use gloves as an intervention, not just gloves, but single use gloves, and I

think that's an important element that needs to be considered because there's a big difference between putting on gloves and performing multiple tasks as opposed to changing your gloves every time you change tasks, and in changing gloves and that also would imply in my mind having to wash and sanitize one's hands prior to putting on the new set of gloves. Otherwise, you're just contaminating your gloves with your hands. So it gets to be a little more complicated.

DR. POTTER: Swami.

DR. SWAMINATHAN: I would like to know if the New York prohibition against bare-hands contact reads exactly the same way as what John was reading?

DR. POTTER: Okay. That's a question perhaps best answered by Jack Guzewich. I'd like to ask Jack to comment on that.

MR. GUZEWICH: The New York code prohibits bare-hand contact with ready-to-eat food. It's that simple. It prohibits bare-hand contact with ready-to-eat food.

DR. NAGLE: No exceptions?

MR. GUZEWICH: No exceptions.

DR. POTTER: Thanks, Jack. Okay. Let me go now to Dane Bernard and then following him, Bob Buchanan.

DR. NAGLE: Can I ask one more question of Jack?

DR. POTTER: Hold on, Dane. Nancy.

DR. NAGLE: Can we ask one more question of Jack?

DR. POTTER: Sure.

DR. NAGLE: Do you have any data that gives you a feel for compliance rate?

MR. GUZEWICH: The compliance rate is mostly based on the level of enforcement by the local health departments. In areas where they've been aggressive about it and the consumers that are aware of it like in the Syracuse area, they have a fairly high level. I mean it's 75, 80 percent probably. In areas where it hasn't been as well aggressively applied, it probably is 50 percent level of compliance I would guess.

DR. NAGLE: Like New York City?

MR. GUZEWICH: New York City or even some of the rural areas where people, you know, don't like government regulations and that kind of stuff, they're more inclined to not to want to do things, but in areas where there's a high consumer awareness and there is active involvement with the health departments, it probably is 80, 90 percent.

DR. POTTER: Okay. I guess we have three placards up on this side. Dane first, then Bob Buchanan, and then Mike, did you have a comment as well?

DR. DOYLE: I did, but go ahead.

DR. POTTER: Okay. Dane.

MR. BERNARD: Thank you, chairman. Actually my comment was not greatly different than what you've heard from the response to John. I think that what is in the food code is not greatly different than what I had suggested earlier. Looking back at the New York data, and we keep referring to that, I can come up with alternative explanations for what is there. I think it's worthless to do that. It is interesting data. It shows a trend. It is not conclusive. I think that would be my scientific opinion of the data.

Does it support a blanket prohibition on bare-hand contact? I think it would be premature to say that what we have on the table right now scientifically says no bare-hand contact, period. Now, that brings me back to the comment I was going to make and then I'm glad John read from the code because I said I think we have enough evidence to say that no bare-hand contact as standard operating procedure is appropriate practice.

Should we say that there can be no deviation from that? That's where I kind of draw the line and say there should be some room for bare-hand contact when there don't seem to be acceptable alternatives and when we can say that can be done without presenting appreciable increase in risk.

It gets back to what risk management strategy do you want to put in place and now we're into policy. But we've been wandering into that all morning. So here we go.

When I said those with the information to look at what tasks go on in the food service retail industry should take a look at those and at least give us some idea of what practices could be undertaken without some barrier, I think that would be helpful and instructive when we get to the National Conference for Food Protection, when this debate is going to be held again, because it does come down to what you do in the field, what is enforceable, what can the local sanitarians do? It becomes an impossible situation in the field to have every local sanitarian look at every practice and come up with an idea as to whether it's okay or not as a variance from the food code.

It's also an impossible task to expect Tom Schwartz and the people at FDA to come up with a list of--a complete list of what is approved variances from the food code. So I'm looking at a recommendation on the policy issue, and I know that's beyond our charge, but what can we do when we get to the National Conference for Food Protection to kind of grease the skids and get over the hump. And my personal feeling is that if we had an idea of the task areas where we can look at something other than a

barrier and implement a gloved hand, something of that nature, that would help the discussion. I hesitate, though, in characterizing my earlier recommendation, as the chair did, as coming up with a list of specific variances because I don't think we can do that.

DR. BUCHANAN: I'd like to follow up several of the comments by Alison and Nancy, who were in turn referring to some of my earlier comments, and try to articulate my concerns a little bit fuller.

Prohibiting or minimizing to the greatest extent possible bare-hand contact seems a very reasonable and prudent approach based on our current information. However, I've been sort of a student of emerging public health problems. And typically public health problems emerge as a result of someone doing something and it having unanticipated consequences. To use Alison's example a little further, we rushed to go out and put air bags in all of our cars and in so doing we wound up killing a bunch of little kids as a result of it because there are appropriate uses and misuses of any of these public health technologies.

My concern is that when we go forward recommending this, be it a complete prohibition or, you know, to the greatest extent possible, and we have no data on its consequences, it seems prudent to also recommend at the same

time that we watch its implementation because if people have a behavior that they are more likely to contaminate their hands in doing their business around the restaurant and don't go over and wash as often, this could be a very serious consequence, and we would wind up with a problem that is different but might be of the same order of magnitude.

So as we go forward, I think we need to look at this, what are not only the immediate public health benefits of these actions, but if don't know what the consequences are, we ought to recommend that someone keep track of them.

DR. POTTER: Mike Doyle.

DR. DOYLE: I only wanted to add that we are going well beyond the science now and I want to get back to the science relative to John's question, and I think as Jeff had indicated, we need to articulate what needs to be done research wise so we can address John's questions.

DR. POTTER: Okay. What I would like to propose now is a break of maybe 20 minutes or so so people can get up and stretch and think for a little bit, and during that time if some of the people who have perhaps not polar extremes on this, because I didn't really hear polar extremes--these are shades of interpretations of the data-- but say, as an example, Alison and Peggy on one side and

perhaps Katy and Skip on the other to see if we can come up with a consensus statement that the whole committee would agree appropriately represents the state of science on this issue. So any objection from the committee to first taking a break?

[Chorus of noes.]

DR. POTTER: I'm glad to see that there are things that this committee can agree on, and, two, this intellectual exercise. Jeff.

DR. FARRAR: Morrie, would it be possible during the break to get copies of that section of the food code?

DR. SWANSON: It's on page 45.

PARTICIPANT: It's very short.

MS. JACKSON: We have run off ten copies of the food code and I'll pass it around for people to look at.

DR. SWANSON: Page 45.

DR. KVENBERG: Chairman, just as we do that, there are--

DR. POTTER: John Kvenberg.

DR. KVENBERG: --in addition to the section of the code, the public health reasons, also it's--I don't have the page number, but there's additional reading, companion reading to that one cite. That's all. Thank you.

DR. POTTER: Okay. Thank you. Alison?

DR. O'BRIEN: The only thing I was going to say is it would have been nice to have had it before we started the discussion because it turns out, listening to John, that there is wobble in the food code right now by saying "as necessary" or whatever. That's different than what New York state is doing.

DR. POTTER: Okay. But it's also a little different than the questions that were posed to the committee.

DR. O'BRIEN: That's true, but it would have been nice if we had known what was in the food code so we would have been--it would have been helpful.

DR. POTTER: Thanks. I agree.

[Whereupon, a short break was taken.]

CHAIRPERSON WACHSMUTH: Okay. Before Morrie finishes up the bare-hand contact, I'm hoping that we will finish before lunch and you will have a free afternoon, if that's the case. You're going to have a couple of tough days coming after this and you're doing some hard work right now. So I'm hoping most of you will like that. It was planned that way. We had some extra room. We thought if this discussion spilled over, we would be able to accommodate it. Morrie.

DR. POTTER: Okay. During break, we received a couple of requests. One was to have a re-presentation of some of the New York data and Jack Guzewich has agreed to do that. Another request was to have John Kvenberg chant in byzantine style relevant sections of the food code. And while that's going on, a draft committee consensus statement on Part III of question three prepared by Katy and Skip and Alison is being typed and will be distributed so that following the two bits of information, the full committee can review that draft and we can open debate on that.

So with that, I'd like to ask Jack to step up to the mike and help us understand the New York data a little better.

MR. GUZEWICH: Is there an extra copy of Dale's handout. I don't have a copy. Do you want me to go through the whole thing or do you want me to answer specific questions? Which would you prefer? The whole thing is going to take a few minutes. If you have some points in mind, maybe that would be quicker, but I'll do it either way you want to do it.

DR. POTTER: Who requested and maybe if we had one specific questions, they could--

DR. O'BRIEN: I think there was confusion or disagreement on a number of points. One had to do with

whether or not there was a documented decrease in foodborne illnesses in food handlers that were in compliance with the New York regulation. A second was was there an overall decrease in foodborne illness associated with food handlers or not, and what were some of other questions? Those are the two key ones and do you mind, Jack, reminding us what position you were in in New York?

MR. GUZEWICH: Yeah.

DR. O'BRIEN: Thank you.

MR. GUZEWICH: I've been with FDA for a little over two years. When I worked for New York was for 27 years and the last 17 years I was there I developed the foodborne disease surveillance program in New York and ran that for the 17 years. So all this data that was collected up until '97 when I left was under my direction.

DR. O'BRIEN: Could I ask one more thing? You mentioned Massachusetts. Could you clarify what you said about that?

MR. GUZEWICH: Let me take that first and then I'll go back to that. I'll go to Massachusetts first. And the 1997 Conference for Food Protection, most of you aren't terribly familiar with how that operates, but it has councils. Let's just say it has councils. It operates in

councils and these councils are advisory to the overall conference. And the councils meet during the conference.

One of the councils is on science and technology and that was the council that was trying to address this issue that you've been talking about here, the last day and a half. And we asked one person to come and present to that council, Dr. Bella Matesh, who is the state epidemiologist for the state of Massachusetts. And he was asked to talk about his experience as an epidemiologist with food worker associated foodborne disease.

That's the context. And the statement that he made there, and then a dialogue, but the gist of it was were they having outbreaks associated with food workers? Absolutely. And what were the contributing factors? And it was basically, he said, bare-hand contact with ready-to-eat food, and he made this statement, that he had had a number of those outbreaks with the agents, mostly viral but also all the bacterial, Salmonella, Shigella, whatever.

And they asked him the statement did you have any outbreaks involved where people were having--not having bare-hand contact with the food? In other words, having gloves on or using tongs or spatulas or whatever and he said no. He did not have any epidemiologic data where he had done case control to show that as being a factor, but he

could say that he had no outbreaks where people were having these kind of outbreaks--where people were protecting, using the barrier methods, the intervention approach basically. That was the gist of Massachusetts and that was the context of Massachusetts.

Now as far as your question for New York is concerned, New York has seen a decline in the number of foodborne outbreaks and some people would like to attribute that to various interventions, and as Dane said earlier, there are probably a number of reasons that that's happened and I wouldn't--people want to put me on the spot of asking me if that could be attributed to this intervention and I wouldn't do that. I don't think that can be done because New York had a number of other interventions we were taking. We put a lot of emphasis on time/temperature control and food safety and a lot of other things.

And it's also probably a function of surveillance. Actually, as many of you know, the public health resource in this country is going down. And New York actually has less of an infrastructure today to do this, to be honest, than they did earlier on. So there could be many things, as Dane alluded to, and I wouldn't begin to tell you that because of this intervention New York had fewer outbreaks. Bob has a question there.

DR. BUCHANAN: Yeah. You presented one graph and a chart entitled "Foodborne Disease Outbreaks by Year: New York State, 1980 to 1995."

MR. GUZEWICH: Right.

DR. BUCHANAN: Do you have that available?

MR. GUZEWICH: Page 11.

DR. BUCHANAN: Page 11. Do you have that chart available to throw up or--well, let me ask the question. If you see a fluctuation in the total number of cases, if you had an intervention that was going to have a specific impact on food handler implicated diseases, what you would anticipate is the percentage of the cases, of the total cases, attributable to food workers would decline if your intervention was successful.

However, when you look at the actual percentage on a yearly basis, it fluctuates all over the place and in effect the highest level of percent food worker cases came after you implemented your program. And how are we to interpret that in terms of the efficacy of the bare-hand contact requirement that you put into place?

MR. GUZEWICH: Okay. And the answer I can give you to that is your first point is well-taken, although the intervention, the regulation itself went into effect in '92, we had an administrative policy prior to that time in the

late '80s on this issue, probably again emphasizing that in '88 or '89--I can't remember the specific year. But you're absolutely right, Bob, that that graph cannot be interpreted in any way to show that there is a trend one way or the other would be what I would tell you. I wouldn't begin to try to do that.

I will tell you that where the outbreaks occurred in New York, they continued to occur in situations where people were not complying with the regulation. Okay. They were having--in these outbreaks, those outbreaks are only that lower set of bars, actually on graph number ten for those of you who have this, where you see those ones that Dale was showing that had the food worker outbreaks, those are only called food worker outbreaks when they're able to identify that there was somebody ill who was involved in preparing the food and that person had bare-hand contact with the food. And the problem has been getting people to comply with that standard just like there is a problem to get people to wash their hands, it's a problem to get people not to come to work when they're ill with these infections. That's been the problem.

The other point I want to make is getting back at the Massachusetts analogy is that through--into '98, I asked them the question in the last several months--but as of the

last time I asked them this question--and we ask this question regularly--have we had any outbreaks in New York state where this intervention was being followed and we still had these kind of outbreaks? And the answer is still no. What did that mean? It means we've had no enteric type of agent that has been involved in a foodborne disease outbreak where they were using tongs or spatulas or whatever or they were using gloves.

So the intervention does seem to, by inverse logic, does seem to have an effect where they comply with it. Also, the question comes up, well, is cross-contamination being an issue if you're getting compliance with this, and they haven't seen outbreaks where that's been shown as a contributing factor. In other words, because this person had gloves on, he or she cross-contaminated the food and that led to a foodborne outbreak.

Now maybe that's errors in the surveillance system and maybe those are happening and surveillance is not getting them because in the '80s and into the early '90s, New York was seven percent of the U.S. population, was reporting that one-third of the foodborne disease outbreaks in the country. Okay. Not because it was a higher risk place but because we had surveillance.

Now it's tailed off a little bit because surveillance has improved in some other states and the outbreaks are down in New York. But I can tell you even that surveillance system has a lot of holes in it and you can miss these kind of subtle changes. That's why I would never try to use it to draw those kind of conclusions.

DR. BUCHANAN: Should we give any credence to the fact that during the years 1980 to 1985 there was a steady increase in the percentage of food worker implicated?

MR. GUZEWICH: Yes.

DR. BUCHANAN: Was there a change that was taking place or is that a difference in the organisms you were detecting?

MR. GUZEWICH: That was an improvement in surveillance. That's because in 1981 and '82 and based on my years of experience long before I got into the role I had in New York, we recognized that food workers were a contributing factor in food outbreaks. And so in our surveillance system, we put a heightened awareness into investigating these outbreaks.

Historically, these kind of outbreaks were sort of throw-aways and a lot of epi-systems never even investigate an outbreak. Oh, that's a viral outbreak. Throw it away. What's the point? And that's what was happening. And so

we put a heavy emphasis on looking for those outbreaks and following through the investigation to its conclusion and coming up with the contributing factors. And what you see there is the effect of looking harder.

DR. BUCHANAN: And now I guess the final question for me to interpret the graph is since you've indicated that this was due to a concerted effort to do surveillance in this specific focus, are the conclusions you're reaching sort of a self-fulfilling prophecy? You've predicted that food workers are going to be a major source of the pathogens; you've targeted your surveillance programs to go out and look at the food workers. And because you have a much higher level of surveillance in this specific factor, you've now pretty much identified that as a major factor.

DR. POTTER: I think the question is observer bias, Jack.

MR. GUZEWICH: Yeah, I understand the question and what I can tell you is this, Bob. We were very concerned in New York in all of our outbreaks, whether they be food worker associated or not, and most outbreaks were still not food worker associated--they were just the single-biggest group--that there not be bias in any of our investigations and we would not count any investigation in these categories

until we had a documented final report in from the local health department of their findings.

And if they could not substantiate their findings as to why they drew their conclusions, then those things did not end up in our summary report. So there is a bias to the effect that we were going out and looking hard for all outbreaks and we were looking hard for those associated with food workers in particular. I can also tell you that in that time period of '82 through '85, we had a huge number of outbreaks of Norwalk virus associated with raw shellfish.

And in the late '80s and early '90s, we had a huge number of outbreaks associated with Salmonella enteritis in eggs. And people said, well, you've got a bias because you're finding all these outbreaks. Well, surveillance finds outbreaks. That's what it's supposed to do.

And when you find those outbreaks, you have to be very objective in your science and make sure that you're not allowing that bias to affect you. You've got to have findings that substantiate those conclusions and we were very fussy about that.

DR. BUCHANAN: Okay. Thank you. That provides the information I needed to interpret the graph.

DR. POTTER: Art.

DR. LIANG: Jack, could you say again what your case definition for a food worker associated outbreak was?

MR. GUZEWICH: We broke the contributing factors down into ill food worker. In other words, we interviewed the individual and he or she acknowledged that at the time that they prepared that food, they were ill with symptoms of gastrointestinal symptoms, vomiting, diarrhea, nausea, et cetera. And/or the person was found laboratory positive for the pathogen that was the agent involved in the outbreak, and when we had that contributing factor, we called that ill food worker. And we had to have one or the other to tick off that contributing factor.

The other one is whether that person, in fact, had bare-hand contact with a ready-to-eat food. Sometimes they admit to that. Sometimes they don't. But where they acknowledge the fact that they prepared the implicated vehicle, the epidemiological implicated vehicle, we would tick off the contributing factor, and we had to have this documented by interview of the person. Then we would say that that was a bare-hand contact with food based on the interview findings.

DR. POTTER: Peggy.

DR. NEILL: I'm trying to reconcile the graph on page eight which deals with breaking your total number of

outbreaks down by contributing factors and then jumping ahead to page ten which has your foodborne disease outbreaks by year and then on the bottom there's number of outbreaks and number of those associated with a food worker and converted to a percent. And you have on page eight that there's only about seven percent of the outbreaks total are that there's hand contact with the implicated food.

Then looking again on page ten, you have the glove order that went in in '92, I'm told. And there's a rather striking decrease by almost about a third in the number of outbreaks, but there's no real change in those due to an implicated food worker.

MR. GUZEWICH: One of the things that's going on there, you got New York state is skewed by two other kind of biases that I alluded to a minute ago. In the early '80s, '82 through '85, we had a huge number of shellfish associated outbreaks that helped the numbers stay high in those years. In the late '80s and early '90s, we had a huge number of Salmonella enteritis outbreaks. We had more of them than the rest of the country put together at that point in time, but by the early '90s, those were tailing off. So part of the tailing off effect you see in those outbreaks were due to the SE in egg outbreaks that we had a total of-- I don't know--20 or 30 a year. We went to zero a year.

Okay. And so that's part of the reason you're seeing that tailing off there in the total number of outbreaks. The food worker ones, you got natural variation from one year to the next and that's because in the early years--you weren't here yesterday, Peggy--we had trouble getting this thing implemented, the requirement implemented by the local health departments in terms of, you know, enforcing it and getting out there, getting the word out and getting the restaurants attuned to it, and then getting the establishments to comply.

So that's why I can't judge that data one way or the other because what I can tell you is when we had the outbreaks, that meant that the people were committing those situations which means the regulation wasn't being complied with. When the regulation was complied with, we didn't have the outbreaks.

DR. POTTER: Other questions for Jack? Dane.

MR. BERNARD: Thanks, Jack. I wonder if you might since you brought up the presentation from the epidemiologists from the state of Massachusetts, which was a very good presentation, if you might discuss some of the other points that came up during that discussion period on the bare-hand contact issue at the national conference?

MR. GUZEWICH: I'm not sure what you got in mind, Dane.

MR. BERNARD: Specifically, the presentation was a very interesting presentation, as is the presentation of the New York state data, but again I hesitate as we did then and as you have today from drawing an absolute conclusion as to what the data means. There's a number of ways of looking at the data, and I think that was the essence of the discussion at the National Conference for Food Protection in '97. And that was not necessarily a one-sided discussion. There were many state representatives who viewed, I think, the issue the same way as they couldn't draw an absolute conclusion. So I just wanted to kind of flesh out the rest of the discussion.

In addition, you've mentioned a number of times that you haven't seen outbreaks where the policy of no bare-hand contact was complied with. Have any of those outbreaks also occurred or have you noticed an absence of outbreaks where handwashing policies were in place and enforced in restaurants or do we have data in that regard as well?

MR. GUZEWICH: No information on the handwashing one, Dane. We weren't collecting that information so I don't know--what I should tell you about that last point you made is that we've--these questions that you're all

struggling with, we've been struggling with, too, for a long time. And FDA has funded through the FoodNet a pilot study on the hands issue in restaurants, picking up on the study that John Kobayashi did several years ago in Washington state, and the state of New York and state of Minnesota are going to be working on a study, prospective study, to--we'll use--a case restaurant will be a restaurant where we've had a food worker associated outbreak. A control restaurant will be other similar restaurant in the community of the same ethnicity of food and relative size of capacity for serving people and the like. And we're going to try to compare the practices in one to the other and we're going to go into greater detail and get to the question you're asking about, the handwashing.

In the New York stuff, we were not asking a handwashing question, Dane, so I can't answer it. But we're going to continue to fund that study with Minnesota, New York and hope that years down the road, we'll have enough data there to answer these the way some of you have been asking around the table today.

As far as the rest of the conversation at the Conference for Food Protection is concerned, Dr. Matesh was the first person to say that he did not have an organized set of data that you could compare and draw overall trends

from if that's what Dane's getting at. And people were trying to flesh out of him, well, what can you say about it, and that's when he said, the point that I made.

And he had been previously the state epidemiologist in Rhode Island and had similar experiences there. He had seen a large number of outbreaks with food worker associated and he really thought that was a significant percentage of the total burden of outbreaks, but he did not have his data compiled in as elaborative way as New York had and he had not done the kind of case control study sort of implicit in what Dane was talking about.

DR. POTTER: Mike.

DR. GROVES: Jack, I have a question. The policy in New York was implemented in '92 or that's when--

MR. GUZEWICH: Yeah, there was a policy about no bare-hand contact that began in the late '80s. The regulation went into effect of August of '92.

DR. GROVES: Okay. Because if you take a look at '92, you're looking at page 11, there's a huge drop in outbreaks, but in '94-95, it looks like it's beginning to increase again. I'm wondering, you know, I can see the first year where then you may have more enforcement of the policy resulting in lower outbreaks. What about--the data

is not shown on here--but do you have any of the data from '96 to the present as to what the trends are?

MR. GUZEWICH: The '97 data they're working on right now so they can incorporate. As Dale mentioned yesterday, he has a graduate student working on it. One of the problems they have is when I left I created a vacancy that's yet to be filled up there--staffing problems in government. And so they don't have a person working on this full time like they had in the past, but if you just look at any of these patterns, you can see all the years you have variation in the number of outbreaks, and this is natural variation.

I wouldn't draw any conclusions up or down about what you see there in those years. The '97 data they're trying to compile now with the grad student so they can--she wants to publish a paper that will be '80 through '97 and they don't have that done yet. So I can't tell you what '97 is going to be.

DR. POTTER: Okay. Other questions for Jack? Jack, thank you very much. Appreciate that. John Kvenberg, are you ready with the code?

DR. KVENBERG: John Kvenberg. Yeah, sure. I can recite the chapter and verse for you. This code, like any good codes that deal with building houses or buildings,

whatever, electrical and plumbing codes, have to have an out in them for a procedure when there's a common sense reason to vary from the way the prescriptive section of a code reads. And the way the food code is set up is that the regulatory authority can grant a variance or modify the existing prescriptive requirement. And several requirements are placed on the individual operator or manager of a firm to document in applying a variance that would be reviewed, judged, and then if warranted, granted by the regulatory authority.

And the requirements or the burden that's put on the process establishment includes actually only three points, but two of them are directly pertinent and one may be. The first is that the requirement that the establishment would have to provide a statement as to the purpose of the variance of the code, then citing the relevant code sections. In this case, the ones relative to hand contact. Second, they need to provide an analysis of the rationale of how the potential public health hazards and nuances addressed in the relevant code sections will be alternatively addressed.

And the third provision speaks to a HACCP plan and it says if required, but they are basically, as the code is

now written, only applied to specific sections that deal with the handling of shellfish or smoked fish.

DR. POTTER: Page numbers?

DR. KVENBERG: Page numbers within the code that speak to variances are 164. Variance is Section 8, 103.10 and page 165 immediately after that, 8.103.11, which is the documentation that I just reviewed of a variance requirement on the establishment.

DR. POTTER: Okay. Now before questions for John, remember that as stated, the charge to the committee is not to evaluate the language of the code. But in your deliberations, should you find that the language in the code is supportable by the data that have been presented, you might want to say that, not necessarily referring back to the code, but if the data don't support a blanket prohibition, but do support the general prudence of avoiding bare-hand contact, what else the data support within that variance and where additional data are needed to clarify what precisely, what conditions need to be met in order to judge the appropriateness of a variance request. So now the floor is open for questions to John Kvenberg about what he just read.

PARTICIPANT: You must have done a good job, John.

DR. POTTER: Let the record show that the committee is really impressed with John's reading of the code.

Okay. During break, Katy and Skip and Alison did try to craft a draft statement that might come from the full committee on the third part of question three. That is being typed and copied and will be distributed to the committee soon so that we can open debate on that.

If Katy remembers the main points--she gave us her copy, but if she can sort of paraphrase it and start people thinking while we're waiting for that draft, that might be useful.

DR. SWANSON: Okay. Help me out, Alison and Skip. See if I get this right. The first part of it says that ill employees are the primary issue that you need to deal with with regard to bare-food contact. That if you prohibit ill employees from working with food, it provides protection of that particular food for the public. In addition, it also prevents transmission to other employees so that that would carry on over time based on data. So the science strongly documents the fact that exclusion of ill employees is necessary and ill employees should not be handling food.

However, the next section says that exclusion of ill employees is not sufficient in and of itself to prevent

disease because there are people who are asymptomatic carriers. It also had a thing in there about how you have to educate employees and management so that they understand that transmission of disease can occur.

Then you go into, yes, handwashing is the second effective method that needs to be implemented, that there are substantial data to show that handwashing is effective in reducing microbes. What else did it say about handwashing? Oh not only does it address human disease agents. It also addresses issues related to cross-contamination of other products and so this must be part of standard operating procedures in any food preparation establishment including employees and management and visitors and maintenance. So that it becomes a way of life, and again non-washing of hands shouldn't be tolerated.

Then we get into the bare-hand contact and that handwashing in and of itself is not going to be sufficient and that minimizing bare-hand contact is also a third means of reducing transmission of disease.

That anecdotal data, and perhaps that's not the right word so we need a sharp pen on that one, suggests that in some jurisdictions where they've implemented a total prohibition of bare-hand contact, that disease may have been reduced, but it isn't clear if that's because people weren't

handling the food or if it was because there was additional education or additional handwashing because of the focus on that.

So it ended up with something like there aren't data to suggest that total prohibition is warranted. However, it should be encouraged in all situations and education to make sure that people understand the consequences and the roles of all three is important. Is that kind of it, Alison?

DR. O'BRIEN: Everything except the total prohibition. I didn't agree to that part, but I agree to everything else you said.

DR. SWANSON: Okay. So do we have copies or is this the only copy?

DR. POTTER: That's the only copy at the moment, but we are going to project it up on the screen so people will be able to read it from there.

DR. SWANSON: Okay. Who are the real wordsmithers that want to take a look at it because I've looked at it enough. Peggy or Dane. Essentially, it was written to answer the questions presented to the committee in the order in which they were presented.

DR. LIANG: Art Liang. I have a question. I'm a little bit uncomfortable with--could New York say something

about the extent to which they feel there was compliance? You know as many of us realize, passing an administrative rule or just having a policy in hand doesn't mean that anything has been done. Mr. Chair, is it okay if I ask New York to say some more about--

DR. POTTER: Sure. Jack.

MR. GUZEWICH: I believe the question you're asking--this is Jack Guzewich with New York, or FDA. I'm answering all these New York questions. I'm sorry. I have an identity crisis here. Your question was what was the level of compliance with the requirement in the state of New York? Is that your question? For this prohibition requirement?

DR. LIANG: Right.

MR. GUZEWICH: Okay. We didn't have really hard data on that. We tried to have information, and as I estimated earlier, in some jurisdictions where there was a lot of attention on this issue, both from consumers and from the regulatory people, I would guess we probably were running 80 or 90 percent compliant. I think there are some other jurisdictions where there is less tendency to comply with the requirements and probably less resources in the health department to enforce it where probably it was a little bit closer to 50 percent compliant. So it varied

some. Overall, across the state, I would say that it was above 50 percent, but I'm not sure it was 75 percent.

DR. LIANG: I guess the situation is sort of reminiscent of what we heard about nosocomial infections. That is you're doing--well, let me make smaller first. In deference to the behavioral scientists, because even though we're talking about behavior, there is some science. There is something called the Hawthorne effect where, if you recall, they turn the lights up in the factory and production improved and then they turned the lights down and production improved. And then there is the other issue that can we isolate this effect to the myriad of things that you were doing to improve food safety?

So I guess that's why I'm a little bit uncomfortable with the language "that there are data to suggest," if we're talking about the New York situation. Maybe there are other data that I'm not aware of. There probably are.

DR. POTTER: Your comments are about the--

DR. LIANG: Yeah, my comment is just about the statement that "there are data to suggest." I guess I'm not totally comfortable with that statement. If I'm the only one, I'll shut up.

I guess the question is were we talking about New York when we're saying that there are data to suggest?

DR. SWANSON: Yeah.

DR. LIANG: Okay. I guess I don't find those data that compelling, but that's just me.

DR. O'BRIEN: I think at the point the statement was written, we didn't have a clarification from Jack. And what he clarified in my mind was that there are no documented instances of foodborne outbreak, worker associated foodborne outbreak, when the individuals involved were complying with the regulation, and that's different than whether there was a decrease in foodborne illness. I think there was some confusion at the time this was written about, in fact, both statements are true from what he said. There was no necessarily decrease in--well, there was, but it wasn't, you couldn't tell whether it was related to the implementation of the regulation, but he did say what I just stated. We all heard him say that. So how you want to change the words, I think they just have to reflect what he said.

DR. BUCHANAN: Morrie?

DR. POTTER: Yes.

DR. BUCHANAN: Just a couple of comments on the second paragraph which is up there now. I think we need a

little bit more clarification in a couple of these sentences. One, the last sentence particularly is a very strong statement that needs some clarification. While we may understand that when we refer to ill individuals, we're referring to people that are suffering from some kind of gastrointestinal disease, this in no way indicates that in this sentence. Are we indicating that someone with a cold or a respiratory disease or a series of other diseases that have nothing to do with fecal-oral transmission should also fall in under this designation?

DR. POTTER: One possible fix for this could be to refer back to the defenses section of the Americans with Disabilities Act in which CDC updates more or less annually a list of diseases that can be transmitted from ill food workers through contamination of food or reference back to relevant sections of the food code that provides a similar although not identical list of conditions. Swami.

DR. SWAMINATHAN: I had problems with the first paragraph or the first sentence, starting with "The root cause of foodborne disease" is somewhat a strong statement. I would suggest modifying that sentence to read as follows: "Available data suggest that a major cause of foodborne disease related to bare-hand contact is handling of foods by symptomatic ill individuals."

And then the next paragraph will start with, "The obvious prevention strategy is to interrupt transmission of foodborne disease." I think stating up front that symptomatic ill individuals are easy to recognize by managers and supervisors. And then in the third paragraph when we talk about asymptomatic individuals, it will follow.

DR. POTTER: Okay. John.

DR. KVENBERG: I hate to be the parliamentarian, but just to pick on the word "ill," I think if you use it in the context of how it's defined in the code, it's okay. Your point, chairman, relative to how the code developed from the communicable disease statement is quite correct, and basically it's health status if the employee is ill. It deals with the disease and your medical condition as it relates to food handling and transmission of foodborne disease. I think it's okay is all I'm saying. It doesn't need to be further defined if it's understood in the context of ill employee relative to the code.

DR. POTTER: Again, the question that went to the committee, however, didn't refer to the code and so I think that we need to be careful--it would be good if the committee were careful in its statements to clearly distinguish that they don't mean people with athlete's foot. Okay. David.

DR. ACHESON: I just want to support Swami's comment about the first paragraph which I thought was a little strong, and an alternative thing that I thought about was individuals infected with foodborne pathogens who handle food are a potentially preventable cause of foodborne disease.

DR. POTTER: Peggy.

DR. NEILL: There has been some history on the committee in the use of phrasing of root cause. We got at this when we talk about the cause meaning a vehicle, but the vehicle was just, you know, the foodstuff or the water, and the issue was really why did something or other become contaminated? So I think the thrust, however we go, whether it's with Swami's, would be to eliminate the word "primarily," because as I see the staging on this, the first sentence or first paragraph is really to say the underlying root cause of foodborne disease related to bare-hand contact is ill people who work with the food because that becomes the logic to proceed to the next paragraph in which I preferred instead of saying "single-most effective," because I thought that would probably begin to throw up flags--we don't really have data for that--is to simply say "the first step," "the first step to interrupt transmission," you know, "by such ill food handlers is to prohibit them from food

handling." Some minor wordsmithing I have in the rest of the paragraph.

The second paragraph I thought would start with instead of "prohibition," a more commonly used phrase is "exclusion of ill workers."

DR. POTTER: Okay. Perhaps we have a couple of proposed edits on the table now. Maybe if we could just stay with that first, that lead sentence, and then the first full paragraph first, and make sure the committee is entirely comfortable with David's comments and yours. Maybe we can hold here and wait on comments on the paragraph that currently starts "Prohibition will not"--

DR. SWANSON: If I may interject, the original paragraph answered the first question before the committee that was presented is do you believe that bare-hand contact with ready-to-eat foods is a contributing factor in the transmission of foodborne illness". The first paragraph was "Bare-hand contact in and of itself does not cause transmission of disease." That was stricken. It wasn't included on your document and then it was followed by the "root cause of foodborne disease related"--the sentence that you saw.

The original thought was, okay, let's answer that question and, yes, maybe what we should do is have an

introductory comment there that says bare-hand contact can contribute to disease. However, the real cause of that disease is an ill individual who handles it with bare contact because it gets to that root cause vehicle what is the issue, but I like that one, too.

DR. POTTER: Peggy and then David.

DR. NEILL: I like the version as it exists simply striking the word "primarily" because it provides the logic sequence that would say step one, keep the ill ones out; step two, I don't mean to discuss the second paragraph, but we do have a logic flow that says in step two that won't solve it all because you have transmission through other individuals.

DR. POTTER: David.

DR. ACHESON: I agree with you, Peggy, that "primarily" should go. I'm having a problem with "the root cause." There is no question that ill food workers transmit pathogens to food and then to the public and to other workers. But we have no clue what the level of transmission is from asymptomatic. It may be tenfold greater. We just-- no data. So I think we just acknowledge that ill people shouldn't be there. They shouldn't be working with food and then move to beyond that. I'm having a real struggle with saying that this is a root cause and primarily and all of

that, just acknowledge it is an issue, but not try to make it that it is the issue or the biggest issue because we don't know that.

DR. POTTER: Okay. Can we see that first paragraph that's now on the screen starting with "Available data suggests"? Is there general concurrence that this is a true and acceptable statement or would be a true and acceptable statement without the word "major" to get at David's point?

DR. LIANG: No, I liked Dr. Acheson's version because he stated--in the opening sentence he states the generality that the issue is not symptomatic ill people alone, it's infected, and then the sub-issues are the symptomatic person to be excluded and then the other issue is the asymptomatic.

DR. POTTER: Okay.

DR. KVENBERG: May I also interject?

DR. POTTER: John.

DR. KVENBERG: At the risk of being punished for trying to help yet again, I think we're in a little bit dangerous ground in that first statement in unraveling other parts of the food code. Going exactly to Arthur's point, let me just reiterate very briefly, it's not only the ones who are symptomatically ill individuals in the code that we

are dealing with relative to restrictions from ready-to-eat foods. It also includes employees who have had symptoms of intestinal illness, those who demonstrate boils or infected wounds, going to staph aureus, employees that have been previously ill that may still be shedding.

It also goes to restrictions from ready-to-eat foods on a family situation if you're living with a person that was ill or if you were not ill but exposed to the outbreak and maybe incubating. So I think symptomatically ill individuals is--if that's the committee's finding, okay, but I think it goes further. Was that what we heard was basically only symptomatic, the available data says only symptomatically ill individuals were responsible? Is that the finding?

DR. POTTER: No, but I don't think that that's what the whole document here says. It talks first about symptomatic and the data to support that and then goes into asymptomatic.

DR. KVENBERG: Will we cover it later then?

DR. POTTER: It's later in the text. The paragraph before you that starts "Prohibition," which Peggy has suggested be changed to "Exclusion" of symptomatic will not prevent because asymptomatic persons exist. Peggy.

DR. NEILL: Katy and I are going to let you go home because we fixed this.

[Laughter.]

DR. NEILL: We're going to a few other regulatory agencies this afternoon to just, you know, finish up the rest of the problem solving.

Why not use a word such as "infected" instead of the word "ill" which gets at the root cause of what we're after here? I think one of the issues is often that it's difficult to explain to people differences between infection, colonization, asymptomatic carriage, illness, disease states, et cetera, et cetera, et cetera. I don't think we really want to go there. What you're really saying, I think, is that infected people can transmit diseases when they handle food.

You don't have to get into it perhaps in the first sentence whether they're symptomatic, ill, et cetera. So as I would look at root cause of foodborne disease related to bare-hand contact is infected individuals who handle food. First paragraph deals with removing ill people from working. Second paragraph says that's not enough because you may have those that are not ill. And you have a second barrier step which is to say handwashing.

DR. POTTER: Comments on that? Bob?

DR. BUCHANAN: With the confusion over the definition of infected among microbiologists and the medical community, let alone anyone beyond that, I would not recommend using the term "infected." I think that what you have here is that the paragraph one and paragraph two should be combined, and it just basically says we know that ill workers are a primary cause of disease due to bare-hand contact. If you have them in the kitchen, get them out of the kitchen, step one.

Step two is not everyone that's in the kitchen that may harbor this pathogen is necessarily overtly ill. So you're going to have a secondary line of defense to take into account these individuals. And if you divide it up that way, I think it's following--if you've got people in the kitchen that are sick, get them out of the kitchen. However, that's not going to solve the problem totally. You have asymptomatic carriers. So you're going to have to have other ways of assuring that we have defenses against these people.

DR. POTTER: I hear Bob and Peggy saying the same thing with the exception of use of the word "infected." It's a difficult word to work around. I mean one could say harboring potential foodborne pathogens within their intestinal tract, but people fall asleep before the end of

the sentence. And I don't know. Perhaps there's another way of saying it. Skip, were you raising your hand? Okay. You just bought the picture on the wall.

[Laughter.]

DR. LIANG: Who's the target audience for this statement? At the Conference, aren't they going to understand this?

DR. POTTER: The Conference is full of crabby people who will argue over a word.

DR. LIANG: Oh, okay.

DR. POTTER: Mel.

MR. EKLUND: The challenge we had before us yesterday on the first paragraph you sent out was the issue currently before the committee is that bare-hand contact of ready-to-eat foods, and we're talking about--I like the sentence food, but the challenge we have is ready-to-eat foods. Should that be changed to ready-to-eat or should we leave it as foods?

DR. POTTER: Perhaps to address the narrower question, it should be changed, but I think if we could sort of stay with the issue of how we're going to describe people with bugs in their gut. Jim?

DR. DICKSON: Not to add more confusion here, but I personally would like the term "infected" because I think

the sequence as it's laid out here starting with infected, specifying symptomatic, then asymptomatic, I like that flow in the document.

DR. POTTER: Cathy.

DR. DONNELLY: Just to come to John Kvenberg's defense here, the food code does lay out very clearly what an ill person is and all the caveats and I think you were trying to simplify our task here, John.

PARTICIPANT: Where is it?

DR. DONNELLY: It's on page--

PARTICIPANT: 23.

DR. DONNELLY: Starting on page 23.

DR. POTTER: John.

DR. KVENBERG: One last try. Dr. Donnelly's intervention, the heading of that title is "Disease or Medical Condition" so perhaps it sounds maybe slightly stilted but as opposed to struggling with redefining something that's been defined, I would propose just saying of individuals having a disease or medical condition as defined in the food code would clearly indicate to the Conference we were referring to Section 2. Disease or medical condition would be the term that's used in the code.

DR. POTTER: Peggy.

DR. NEILL: I was going to ask Bob, we had discussed this terminology at a Codex meeting awhile back and I thought it was a question that came up and that got kind of universal agreement that infected just meant infected. It was indicative that the person had an organism on a usual mucosal surface and was not meant to convey clinical symptomatology.

DR. BUCHANAN: More and more we're moving towards it simply in the case of an intestinal organism that the intestinal tract has been colonized--

DR. NEILL: Right.

DR. BUCHANAN: --independent of symptoms.

DR. NEILL: Right.

DR. BUCHANAN: So if you're going to use infected, we need to make sure that we put the caveat whether we're talking about symptomatic or asymptomatic carrier individuals.

While I've got the microphone, Morrie, another issue I'd like to raise on that paragraph, and it's like smacking, you know, Mom and apple pie and all that, while the sentiments about education are appropriate later on in terms of what are the issues related to implementation, I think that they're just add-in sentences where they are in the second paragraph and the third one also, that they ought

to be moved, that one of the factors that are going to affect our ability to achieve this is going to be education.

DR. POTTER: Okay. Thanks, Bob. Alison.

DR. O'BRIEN: I was just going to say to Peggy that--back to the issue of infected--first of all, I think we should use the code definition. I think that will simplify things, but infected to me means colonized, but it doesn't necessarily mean a pathogen. So that makes it even more confusing. I mean that is the general--infected means it's there. It doesn't mean necessarily disease and it doesn't necessarily mean a pathogen at least in my mind. Therefore, if the three of us don't agree, that's the point.

DR. BUCHANAN: Right. That was my point.

DR. POTTER: Okay. Peggy, Katy, can we construct the first sentence using the language from the code?

DR. SWANSON: I don't know the language in the code.

DR. NEILL: What page?

PARTICIPANT: Page 23.

DR. KVENBERG: Page 23.

DR. NEILL: Subpart 2.201.

DR. KVENBERG: 201. 2.201 as defined would be good.

DR. POTTER: I think if we look at the words that are on there, the last line that starts with "symptomatic"-- well, the last line, "symptomatic ill individuals," if we replace that line is "the handling of ready-to-eat foods by food workers with"--John?

DR. KVENBERG: "A disease or medical condition as defined in Section 2.201 of the Code." Section 2-201.

DR. POTTER: David.

DR. ACHESON: I'm coming back to my previous problem. I'm still struggling with the word "major." I'm wondering if important preventable could be used instead?

DR. POTTER: All right. Let's put that on the table.

MR. BERNARD: How about "fundamental"?

DR. POTTER: Well, okay, let's first judge the acceptability of David's intervention "important preventable" instead of "major." Alison?

DR. O'BRIEN: I agree. No, I think preventable because that's what we're trying to do here. I think that's a good term to use and I understand the "major" issue for a variety--among other things, if you look at graphs, maybe it isn't. So if you say preventable, then it leads us through the rest of the statement. I like that.

DR. POTTER: Okay. Comfort level? Skip?

DR. SEWARD: Well, I'd like to know what the prevention is. I thought we talked a lot about the fact that a lot of people don't know that they're, you know, the fact that they're symptomatic carrier, they may not recognize that right away. So to me you really don't need any adjectives there. If you want to simplify it, you just say it's a cause. Unless you have a compelling reason that you feel like you have to have some adjective there to make it sound like more than it is.

DR. POTTER: Okay. Let's take that one. Available data suggests that a cause of foodborne disease related to bare-hand contact. What's the comfort level with that? Katy?

DR. SWANSON: Not to beg the question, but can somebody tell me what the other cause of foodborne disease related to bare-hand contact would be?

DR. POTTER: Well, during the past couple of days, we did talk about the transfer of pathogens from a contaminated surface to the ready-to-eat food.

DR. SWANSON: Okay.

DR. POTTER: Bob?

DR. BUCHANAN: I would like to support the use of "preventable" because the next two paragraphs are really strategies for prevention. And that's what the document is

laying out is how do we prevent this. So I don't really see the problem with identifying it as a preventable.

DR. POTTER: Okay. Let me ask a point of clarification, Bob. When you say it's preventable, do you mean 100 percent preventable necessarily? Or when you say preventable, do you mean that some portion of those diseases can be interrupted?

DR. BUCHANAN: I assume that--I don't assume 100 percent on almost anything.

DR. POTTER: Okay. Alison?

DR. O'BRIEN: How about potentially preventable? If you really want to get to it, that's what we're talking about. How do you prevent but it's potent--I mean if that's what you want to say? If you're worried about whether it's 100 percent or not, we're just saying if you can get workers out of there, we can potentially prevent disease.

DR. POTTER: Okay. We have a vote here for available data suggests that a preventable cause, with no judgment on whether it's an important cause, unimportant cause, no judgment on whether preventable is 100 percent or not. Comments? Katy?

DR. SWANSON: As the lead in to this entire section, can we go back to the original question put before the committee and think of words that we can use to answer

that question? The question was do you believe that bare-hand contact with ready-to-eat foods is a contributing factor in the transmission of foodborne disease? Perhaps the best sentence would be we believe that bare-hand food contact has contributing factors that can contribute to disease. And the second question was--leads into the three things that we identified.

DR. POTTER: Okay. So--

DR. SWANSON: I don't think that answers the first question presented to the committee.

DR. POTTER: Okay. To get at--let's see if I understand Katy's proposed first sentence so that we can-- data presented to the committee--"Based on data presented to the committee, NACMCF believes that bare-hand contact with ready-to-eat foods is a contributing factor in the transmission of foodborne illness."

PARTICIPANT: Can be.

PARTICIPANT: What was the rest?

DR. SWANSON: "Contributing factor to the transmission."

DR. POTTER: Okay. First sentence as it's presented there okay to the committee? Peggy?

DR. NEILL: Would just change the verb to finds, "NACMCF finds."

DR. POTTER: Okay. Change "believes" to "finds."

DR. SWANSON: And instead of "is" "can be."

DR. POTTER: Okay. The last modification okay to everyone? Swami.

DR. SWAMINATHAN: I would just delete one of the NACMCFs and say "based on data presented, the National Advisory Committee finds."

DR. POTTER: Okay.

DR. BUCHANAN: The alternative would be to specific--well, no, leave it the way it is.

DR. POTTER: Peggy.

DR. NEILL: Just try to make it a little stronger. Katy and I both said going from "is" to "can" sounds a little weak, but maybe if you just "can contribute." "Bare-hand contact with ready-to-eat foods can contribute to the transmission of foodborne disease."

PARTICIPANT: Yes.

DR. POTTER: Okay. I hear change and one agreement. Is the committee comfortable with that? Okay. Let's move to the second--uh?

DR. O'BRIEN: The closer to lunch it gets, the more agreeable we are.

DR. POTTER: Okay. Because there are some important issues later in this, let's agree to that and move

on to the rest of that paragraph now. As it's written, Bill?

MR. SPERBER: Yeah. Throughout this document, do you want to refer to foodborne disease or foodborne illness?

DR. POTTER: I'm not sure that it--well, it certainly doesn't matter to me. What's--

MR. SPERBER: In all of your questions, it's illness and I thought of disease as being more contagious thing. Illness is more, you know--

PARTICIPANT: The statement said illness. I don't know if you want to repeat it.

DR. POTTER: Okay. We can stick with the word "illness" if that's the committee's pleasure?

DR. BUCHANAN: Morrie, can I recommend that in terms of continuity of thought that the second sentence in your first paragraph should really be the first sentence in the second paragraph?

DR. POTTER: Mike.

DR. DOYLE: I would suggest that we now address the second question and skip "available data suggests" down because that's really question three. And then address the next question. If so, can transmission of foodborne illness via bare-hand contact with ready-to-eat foods be interrupted?

DR. POTTER: That question can be addressed by putting the word "preventable" back in as it is there. I mean available data to suggest--where was it? David's earlier intervention.

PARTICIPANT: It's still there.

PARTICIPANT: Available data suggest that a preventable.

DR. POTTER: That a preventable cause. Okay. Okay.

DR. DOYLE: But not speak to excluding ill people at this point. I mean--

DR. POTTER: Okay. Okay.

DR. DOYLE: That comes later.

DR. POTTER: All right. So Michael's suggestion then is an additional sentence at the end of paragraph one that answers the second question does the committee believe that this transmission can be interrupted?

DR. BUCHANAN: I think the sentence as it reads now by the use of the term "preventable" indicates that it can be interrupted.

PARTICIPANT: Yeah, I agree.

DR. POTTER: Okay. But I think that Michael's point is that by using the word "preventable" associated with food workers with disease or medical condition only

addresses that one strategy. Is the will of the group that that's an adequate answer for the second question?

DR. SWANSON: How about this transmission can be prevented, period?

DR. POTTER: Okay. Proposal on the table. Second sentence in the first paragraph--this transmission can be prevented? Okay.

DR. SEWARD: In many instances this transmission can be prevented. I think some people have the interpretation that like I do that if you say it's prevented, that means that it's 100 percent, even though there is no reason why you shouldn't be able to prevent it. Just put a qualifier on there.

DR. POTTER: So in principle, this transmission can be prevented?

PARTICIPANT: Interrupted.

DR. POTTER: Interrupted.

DR. SWANSON: Interrupted.

DR. POTTER: Comments? Acceptable. All right. Going on to the second paragraph then? The third paragraph?

DR. BUCHANAN: Again, I think the sentence that says this is a lofty goal requiring education of food handlers is not--should be moved to later in the document.

DR. POTTER: Okay. Reaction to Bob's suggestion?

DR. SWAMINATHAN: Agree.

DR. POTTER: Swami agrees. Roberta agrees. Okay.  
General consensus that the end of that paragraph should be  
moved?

DR. BUCHANAN: Not the end, that sentence.

DR. SWANSON: That sentence.

DR. POTTER: Okay. The obvious.

DR. BUCHANAN: And it should be "an obvious  
preventive strategy."

DR. POTTER: Okay. So "an obvious preventive  
strategy to interrupt is by prohibiting" or "is by the  
prohibition."

DR. BUCHANAN: "Is the prohibition."

DR. NEILL: Okay. "Is the exclusion."

DR. POTTER: Okay.

DR. NEILL: You need an "is". We need a verb.

DR. BUCHANAN: LeeAnne, it's "is the"--that's it.

DR. POTTER: John Kvenberg.

DR. KVENBERG: Well, I had it beat into me early  
in life that food handling probably isn't a really good word  
in that sentence to use so food preparation or something  
like that.

DR. POTTER: Okay. From food--well, wait a  
minute.

DR. KVENBERG: Preparation. The concept we're struggling with is ready-to-eat foods; is it not?

DR. POTTER: Okay.

DR. BUCHANAN: John, I would disagree. In this case, we are specifically talking about them handling the food.

DR. POTTER: Okay. Sense of the committee?

DR. FARRAR: I prefer food workers, but--

DR. POTTER: Well, but exclusion of these individuals from working on food; is that what you mean, Jeff?

DR. FARRAR: No, by ill food workers instead of food handlers.

DR. POTTER: But it's not food handlers. It's from food handling.

DR. KVENBERG: Again, going back to the language, it may be an exclusion or it may be a restriction. So we got to be a little bit careful here on what it is or isn't.

DR. POTTER: Okay. Now, that's the language in the code, but that's not what I heard the committee say. What I heard the committee say was by exclusion. Nancy?

DR. NAGLE: Can I ask a question? Maybe this will help us make that decision. Do we believe that we can interrupt the transmission from say an asymptomatic carrier

by some of the means other than exclusion? Do we think that gloves or using of utensils will successfully keep that individual from transmitting the disease because if we do, then John is right. Maybe restriction or something is a better term there.

DR. POTTER: Okay. I have two votes now for saying exclusion or restrict--is the exclusion/restriction of these individuals from food handling. Now we get back to Jeff's question about whether "handling" is the word we want there.

DR. FARRAR: And one additional consideration. It may not be just those who are actually handling the food. It may be those who are cleaning the kitchen or handling the silverware. I think we need to look beyond just those that handle the food.

DR. POTTER: Individuals from working on ready-to-eat foods. I don't know. Jim?

DR. DICKSON: Maybe the word or the words that we're looking for is "restriction of these individuals from contact with ready-to-eat foods."

DR. POTTER: Okay. Mike?

DR. ROBACH: Or the ready-to-eat environment.

DR. POTTER: We don't eat the environment.

DR. ROBACH: The environment you got product, contact surfaces, you have wrappers, you have utensils. These individuals should not be in contact with anything that will come into contact with the ready-to-eat food. They shouldn't be in the ready-to-eat environment.

DR. POTTER: Stephanie.

DR. DOORES: Where do these people go if they report to work ill and if they're not put on the food line, then they might be doing things like wiping up tables or things like that, which is a contact surface which they could easily transmit and not be in the ready-to-eat food. So we have to be aware of that.

DR. POTTER: Okay. Let's suggest some words to address this?

PARTICIPANT: I think contact is broad enough that we wouldn't need to add any more qualifiers to it.

DR. POTTER: Okay. So individuals from contact with ready-to-eat foods.

PARTICIPANT: Contact would be everything from plates and utensils to anything.

DR. POTTER: John?

DR. KVENBERG: I'm just reverting back to what I'm reading. These restrictions basically say the duties that would be assigned would be restrict employees from working

with exposed food, clean equipment, and unwrapped food. I'm paraphrasing. I'm cutting it down to something, but basically that's it.

DR. POTTER: Does the word "contact with ready to eat foods" get there?

DR. KVENBERG: Getting to Jeff Farrar's point, it also includes anything that would be secondarily involved to include the clean and sanitized equipment, utensils, and linens.

DR. POTTER: Is that for the sake of the linens or is it for the sake of the contact with the food?

DR. KVENBERG: I think it--well, the intention was--I don't know. Jeff can speak to it perhaps better than I can, but the idea was to prevent touching the fomite that would go to your mouth to give you the disease in the case of Hepatitis A.

I'm just merely pointing out that's the exclusions, to reduce the risk. Okay. It's not just the food itself. It's also direct food contact surfaces that would affect the health of the person eating the meal.

DR. POTTER: Okay. Exclusion restriction of these individuals from contact with ready-to-eat foods or food contact surfaces?

DR. KVENBERG: Yes.

DR. POTTER: People like that? LeeAnne, type it in before they change their minds. Okay. This prevents not only transmission to the public but also other employees who can extend the total exposure time.

DR. NEILL: Should be "and food contact surfaces."

DR. POTTER: Change the "or" to an "and." Okay.

DR. FARRAR: Can we briefly revisit handlers versus workers one more time?

DR. POTTER: Sure. By ill food workers.

PARTICIPANT: Food worker or food employee perhaps an alternative to handler.

DR. POTTER: Just change "handlers" there to "workers." I think now we're talking about contact so that gets at this issue of the fact that the food workers are actually handling the food. People like the last sentence in that paragraph? Okay. Let's go to the next paragraph. Peggy has already suggested changing the word "prohibition" to "exclusion/restriction." Scott, who had to leave, suggested that we mention food workers with family members at home who are ill. Is this the place to put that? Nancy?

DR. NAGLE: The code specifically talks about those. In our earlier definition, when we say anyone there, the code talked about ill family members.

DR. POTTER: Okay. So Scott's point is taken care of by the definition to which we refer.

DR. NAGLE: Uh-huh.

DR. POTTER: Okay. Do the data support that handwashing is the second-most effective method? Is that what we want to say there or that that's the second barrier being considered by the committee?

DR. O'BRIEN: I think we need to say the second barrier because we don't talk about how effective the first point is.

DR. POTTER: Okay.

DR. SWANSON: Or the second method to prevent transmission.

DR. POTTER: Okay. Second method.

DR. LIANG: I second that.

DR. POTTER: Okay. We have a couple of options on the screen. Thorough handwashing is the second method, the second control strategy, the second barrier?

DR. LIANG: Another method.

DR. POTTER: Is another method.

PARTICIPANT: Prevention strategy.

DR. POTTER: Is another prevention strategy. Okay. I hear two votes for prevention strategy. Anybody else want to weigh in on a choice of words there? Peggy?

DR. NEILL: Morrie, I think this is what I saw coming as an entanglement, the point that we're at now, by not dealing with these considered steps. I can't imagine that you would do handwashing and not exclude ill workers. So the change could be without getting--as David pointed out, we don't know what proportion of transmission comes from the ill versus the asymptomatic, blah-blah-blah, but if you just, the paragraph that starts "An obvious prevention strategy" or something, if you go "The first step of the prevention strategy."

DR. POTTER: Well, is the first--

DR. NEILL: And then this part becomes "The second step."

DR. POTTER: Okay. But we're calling this the second.

DR. NEILL: Yeah, but not the way--you don't have a first, and if you say it as a second control method, that begins to sound like you've got two options. And I don't think that's what we're saying. Perhaps it's implied, but I thought we were saying the first step is this and you have a second barrier. You have a second step to undertake.

DR. POTTER: All right. But let me ask you, Peggy, could as a stated policy of food service establishment say everybody has got to wash hands, first

barrier, wash hands. Second barrier is if you're ill don't come to work instead of the other way?

PARTICIPANT: No.

DR. NEILL: I didn't want to use the word "prerequisite," but I would think exclusion of ill workers is--

DR. POTTER: Exclusion is always first, is always option number one or is always step number one. Bob.

DR. BUCHANAN: Can I recommend a way around this is to--can I go back to the second paragraph?

PARTICIPANT: That's what this is.

DR. BUCHANAN: No, the next one. Third. And start that, modify the first sentence to read "exclusion/restriction is not sufficient to ensure prevention of all foodborne disease due to the presence of infected individuals with no overt symptoms."

DR. SWANSON: It says that already.

DR. BUCHANAN: This more explicitly, the modification here is to more explicitly state that the first intervention is not sufficient to provide the level of assurance that we expect.

DR. POTTER: Okay. Katy has just pointed out that in the charge to the committee, in addressing question

three, it says individually or in combination which may not require us to do this in a stepwise manner.

DR. SWANSON: Does anyone on this committee believe that we should convey to people that there is an option? You can pick one from Column A, one from Column B, or one from Column C? Or do we have to have them in combination? Maybe that's what we should address.

DR. POTTER: Okay. All right. Does the committee feel that these three barriers need to be used in concert rather than as alternative strategies?

[Chorus of agreement.]

DR. POTTER: Okay. Now, if we agree that all three are appropriate, are they still sequential or since all of them are there, does it matter which we call number one? Peggy?

DR. NEILL: I think only in logic.

DR. POTTER: Okay. I tried that once.

DR. NEILL: There's parallels to hospital-based infection control for control measures.

DR. POTTER: Okay. Roberta.

DR. MORALES: The only difficulty I have with the sequential presentation is the way it stands that to me it seems to pertain only to these steps as they relate to transmission from ill food workers, but it doesn't address

that whole issue of transmission in general, which may not be related to ill food workers. So--

DR. POTTER: But I think we agreed earlier that the data that were presented to the committee really only addressed this one issue, the issue of organisms inherent to the food worker.

DR. MORALES: To food workers.

DR. POTTER: Okay. LeeAnne, where are we on paragraph one? Have you made any changes in paragraph one? No. Any changes in paragraph two? All right. The first change that's been introduced is in parentheses "(the first) preventive strategy" instead of "an obvious preventive strategy." What's the will of the group?

[Chorus of "the first."]

DR. POTTER: Okay. I hear some votes for the first preventive strategy. Dane?

MR. BERNARD: That would be my choice. I view that as a stand-alone. Handwashing and no bare-hand contact are where we're talking about what is the mix? What's the appropriate mix? I would view that as the first and that's fine. And when you get back to the next paragraph, I'd like to suggest some language on the handwashing.

DR. POTTER: Okay. Any disagreement with saying "the first preventive strategy to interrupt"? Anybody disagree? Peggy?

DR. NEILL: I don't disagree. The wordsmithing grammatically to make the sentence work would probably be "The first preventive strategy to interrupt transmission of foodborne illness by bare-hand contact" or something like this is--the "by ill food workers" is to come after "exclusion/restriction."

"The first preventive strategy is the exclusion/restriction of ill food workers from contact with ready-to-eat foods and food surfaces."

DR. POTTER: Okay.

DR. NEILL: I think it still needs a little bit, but--

DR. POTTER: Okay. "The first preventive strategy to interrupt transmission of foodborne illness is the exclusion/restriction of ill food workers from contact." Everybody--anybody disagree? Okay. Let's go to the next paragraph.

"Exclusion/restriction" is where we--"is not sufficient." "Exclusion/restriction is not sufficient to ensure the prevention."

PARTICIPANT: To prevent.

PARTICIPANT: The prevention of foodborne illness will not prevent all transmission.

PARTICIPANT: Yeah, to prevent all.

PARTICIPANT: To prevent.

PARTICIPANT: Cuts a lot of it out.

DR. POTTER: Okay.

DR. BUCHANAN: Exclusion/restriction alone is not sufficient to prevent all transmission from infected individuals due to existence of asymptomatic carriers.

DR. POTTER: Wait a minute. Wait.

"Exclusion/restriction alone is not sufficient to prevent all transmission of foodborne illness from infected food workers because of asymptomatic carriage." What else is needed in that sentence?

PARTICIPANT: Just a minor thing, but would it be better to say "an exclusion/restriction policy alone is not sufficient"?

DR. POTTER: I would rather avoid the "p" word, yes. Okay. Now, thorough handwashing is the second barrier prevention strategy method, control strategy? What's--Dane?

MR. BERNARD: Can't we just say that thorough handwashing is an essential prevention strategy or an essential control method to prevent transmission of foodborne disease? I don't think we want to put an ordinal

ranking in there. Whether we're talking about gloving or not, we're going to be talking about washing hands before you put on the glove.

DR. POTTER: Okay. So sort of the second order prerequisite. So thorough handwashing is--

MR. BERNARD: We just say it's an essential part of the program.

DR. POTTER: Okay. Okay. Now, Peggy, does this destroy the logic flow?

DR. NEILL: I think--

DR. SWAMINATHAN: I would replace the "essential" with "effective." Just say "thorough handwashing is an effective method to prevent."

DR. POTTER: Okay. There's some disagreement being voiced. Nancy?

DR. NAGLE: Yeah. I think we all made it really clear that the use of gloves without handwashing was not an effective strategy and that handwashing is actually essential. That is the key piece is we want handwashing there.

DR. SWANSON: How about "Thorough handwashing is essential to prevent transmission"?

DR. POTTER: Okay. Now do we want to say "thorough and frequent" or just "thorough"? Once a day

thoroughly cleaning your hands or maybe just on Sundays. I don't know. Do we need any statement of frequency?

DR. O'BRIEN: No, because then we'll have to define it.

DR. POTTER: Okay. If we make mention of frequency, do we have to define how often? Katy, you're shaking your head. What does that mean?

DR. SWANSON: Depends. You can't define a frequency because it depends on what the individuals are doing.

DR. POTTER: Okay. So I'm hearing perhaps we don't want to go there. Thorough handwashing is all we need.

[Chorus of agreement.]

DR. POTTER: Agree?

PARTICIPANT: That's good.

DR. POTTER: Art. Okay. Proceed.

MR. BERNARD: Next sentence should be again--it's another one of those--don't bother changing it. Just get rid of the whole sentence.

PARTICIPANT: Move it.

DR. POTTER: Okay. All right. Okay. "Not only does handwashing minimize the potential for transmission of human borne disease agents, it also minimizes cross-

contamination from raw foods or from sources of contamination." It could be garbage lids. What words do we want?

MR. BERNARD: Why don't you end the sentence after "cross-contamination."

[Chorus of agreement.]

DR. POTTER: Okay. "Lack of adequate handwashing should not be tolerated."

MR. BERNARD: That doesn't add anything. That's a policy statement.

DR. POTTER: Okay. Do we make that same policy statement about ill food workers?

MR. BERNARD: Well, I had some concerns about that.

DR. POTTER: Okay. Is the rest of the paragraph okay? Anybody want to make changes?

DR. BUCHANAN: No, but why don't we revisit the paragraph before it?

DR. POTTER: He's headed in the wrong direction. LeeAnne, please go up and see if that statement is up earlier.

DR. KVENBERG: Chairman, just to be consistent with earlier wording "handlers," I think you used "workers,"

individuals entering the food preparation area. I think we changed it.

DR. POTTER: Oh, okay. Yes. That becomes "workers" and then take care of Bob's issue on the earlier paragraph. "Science strongly supports that preparation of food by ill individuals should not be tolerated." Do we want to keep that in or as a statement of science or do we want to exclude it as a policy statement?

PARTICIPANT: Well, the science, that's okay.

DR. POTTER: That's okay. I hear a vote for it's okay.

DR. BUCHANAN: I would change the statement here instead of being tolerated, "Science strongly supports that preparation of food by ill individuals should be controlled, avoided."

DR. POTTER: Presents a risk.

PARTICIPANT: Shouldn't be allowed.

PARTICIPANT: Or presents risk.

PARTICIPANT: Don't do it.

DR. POTTER: Okay.

DR. SWAMINATHAN: Do you see a need for "Science strongly supports"? Why not start with "Preparation of food by other individuals should not be allowed or tolerated"?

PARTICIPANT: Because they want a scientific statement.

DR. POTTER: Okay.

PARTICIPANT: Or maybe just say presents a risk.

DR. POTTER: Do we want to say--one, who wants to eliminate that sentence?

[Show of hands.]

DR. POTTER: Okay. I see some votes for eliminating the sentence. Who wants to keep it as it is? Okay. Nobody wants to keep it as it is. Who wants to change the end of it to supports "The preparation of food by ill persons presents a public health risk" or words to that effect?

[Show of hands.]

DR. POTTER: Okay. I see a preponderance would like to eliminate the sentence all together.

DR. KVENBERG: Another alternative though.

DR. POTTER: John Kvenberg is going to propose an alternative.

DR. KVENBERG: Well, just the end of it--I think "tolerated" is the offensive piece because it goes to policy. "Should be avoided" or something of that nature. "Science strongly supports that preparation of"--

PARTICIPANT: That's not science.

DR. POTTER: That represents no change. I mean it's--

DR. KVENBERG: Well, I was just going after--I guess my sensitivity was "tolerated" goes to a policy.

DR. POTTER: Okay. Jim.

DR. DICKSON: Well, I think what we're trying to say is that the scientific data supports that preparation of food by ill individuals or workers or whatever is a source of foodborne disease.

DR. POTTER: Okay.

DR. DICKSON: And that takes the judgmental tone out of the sentence. That's what science says. That's what the data support.

DR. POTTER: Okay. Peggy?

DR. NEILL: I personally am okay with this to just take off the "Science strongly supports" because I think we have something like that at the front of the document, but change "tolerated" to "allowed." But the other fix is to just flip the sentence to state that "Ill individuals should not prepare or handle food."

DR. POTTER: Bob?

DR. BUCHANAN: Okay. The reason why I have problems with this and getting rid of "Science strongly supports" is we didn't see strong support from this. You

couldn't even prove that there weren't interventions that could be used in terms of letting these sick workers work. We heard a number of people say that the scientific data just wasn't there and now to come back and say that "Science strongly supports," we have a lot of very soft data and we don't have anybody that's really studied and says if you have these people and they don't follow the--even in the presence of the other interventions that we're talking about, they still represent an unreasonable risk. We didn't have that.

DR. POTTER: Okay. That sounds like a vote to eliminate that sentence.

PARTICIPANT: That's okay.

DR. POTTER: Anybody desperate to keep that sentence in? Peggy?

DR. NEILL: Right.

DR. POTTER: Swami? Okay. How would you change it to or would you change it at all in response to the statements that are on the table? Katy?

DR. SWANSON: Ill individuals should not prepare food.

PARTICIPANT: No.

DR. POTTER: Nancy?

DR. NAGLE: I think we'll come back to what Bob said and my earlier question of is appropriate handwashing, gloving, and whatever sufficient to keep an asymptomatic person from spreading it? And then the question is if it can do it for an asymptomatic person, what about an ill person? So--and we didn't see, as Bob said, enough data. Peggy?

DR. NEILL: We were just trying to say that the sentence of ill persons shouldn't prepare food is the food code, page 23 to 25.

DR. POTTER: But this is supposed to be based not on the food code but based on the scientific data or the--

DR. NEILL: Okay. But I mean from whence came the food code? I mean aren't we still--

[Laughter.]

DR. POTTER: Tom Schwartz is--you know, that's not what we're asked here.

DR. SWANSON: But we could say, if we go back to the thing, we could say that we did see evidence that ill workers presented a risk.

DR. POTTER: Okay.

DR. SWANSON: That's about as far as we can go with the statement though, that ill workers do present a

risk. We saw the guy with his arm in the thing. He made it--

DR. POTTER: Okay. Bob?

DR. BUCHANAN: I think if you just take off--if you start the sentence "Preparation of food by ill individuals should not be tolerated," it's a management decision that's being made here. Don't try and hide it with a reference to science. Just say we recommend that they not be done. I mean we just didn't hear the science yesterday to allow us to try and say that we heard--

DR. POTTER: Bob, what's wrong with Nancy's statement?

DR. NAGLE: Ill food workers present a risk.

DR. POTTER: Ill food workers present a risk.

DR. SWAMINATHAN: There's nothing wrong with it, but it's stated--

DR. BUCHANAN: Well, no, I think what you have to state there is that ill food workers represent an unacceptable risk.

DR. POTTER: Stephanie.

DR. DOORES: I was just going to argue to what Nancy said about there might be a possibility in difference of shedding of the organism between an asymptomatic and an ill person so that those intervention strategies could

prevent an asymptomatic but not necessarily prevent an ill person.

DR. POTTER: Okay. I'm left with the sense that this sentiment has already been expressed and we could eliminate the sentence and move on.

[Chorus of yeses.]

DR. POTTER: And if we judiciously apply duct tape to Dr. Buchanan, we may actually--less is more.

PARTICIPANT: I have some in my briefcase.

PARTICIPANT: Do you have a meeting to go to?

DR. POTTER: Okay. What's the pleasure of the group? Can we eliminate this controversy by chopping the sentence? She's added. Okay. LeeAnne, put us back to where we were before we digressed.

PARTICIPANT: I already know it. This sentence doesn't tell me anything I don't know.

DR. POTTER: Okay. It's gone. Okay. We are in the paragraph that starts "Exclusion/restriction alone is not sufficient to prevent all transmission of foodborne illness from infected food workers due to"--because there are. Well, okay.

PARTICIPANT: Yeah, I know what you're saying.

DR. POTTER: Because there are asymptomatic carriers. Thorough handwashing is essential to prevent

transmission of foodborne disease by infected food workers. Not only does handwashing minimize the potential for transmission of human borne disease agents, it also minimizes cross-contamination. We've modified the sentence. I'm not sure it says what was intended.

Do we need to say it also minimizes cross-contamination by other foodborne pathogens?

PARTICIPANT: It's actually from other sources.

DR. LIANG: What if we started that paragraph off with "Handwashing be a standard operating procedure for all individuals"?

DR. POTTER: Okay. Art, please speak into the mike.

DR. LIANG: Maybe it wasn't such a good idea. I got silence. How about if we started that paragraph with "Handwashing should be a standard operating procedure"? You know, exclusion/restriction alone--you know, because there are asymptomatic carriers and then the added benefit of cross-contamination.

DR. POTTER: Okay. Art is suggesting putting a topic sentence at the beginning of--

DR. LIANG: Just move the last sentence on handwashing. I don't know. I'm not going to fight this. It's just stylistic.

DR. POTTER: Okay. Art has suggested making the last first. Jeff?

DR. FARRAR: I just have a little bit of concern about the sentence being a policy statement that this should be standard operating procedure and not only that, but individuals entering the food prep area. I mean there are a lot of other conditions where people should be washing their hands. I don't see any value in this sentence. It leads to a policy statement.

DR. POTTER: All right. So we can take care of both of these issues by eliminating the sentence. This could be a short document by the end.

DR. GROVES: I'll second that.

DR. POTTER: Okay. I have two votes to just eliminate the last sentence in that paragraph. Anybody want to keep the last sentence? Nobody likes it. All right. It's gone.

Now, does the paragraph as it stands say what we want it to say? Okay. Dane?

MR. BERNARD: Minor modification to eliminate green squiggly things.

DR. POTTER: Okay.

MR. BERNARD: Handwashing minimizes the potential for transmission of human foodborne disease agents and minimizes the potential for cross-contamination.

PARTICIPANT: It doesn't work--we have "only". It doesn't work.

DR. POTTER: Okay. Now you need to eliminate the "not only does" and upper case the "H".

MR. BERNARD: Handwashing minimizes.

DR. POTTER: Now, the way you've restructured the sentence, Dane, it says "Human foodborne disease agents which would include those of human origin and all others." Do we still need the words "and minimizes cross-contamination"?

DR. NAGLE: When you say from other sources.

DR. O'BRIEN: Cross-contamination from other sources.

DR. POTTER: Okay. I guess but human foodborne disease agents is anything that causes foodborne disease. The way it was originally structured, it was human borne disease agents.

PARTICIPANT: Take that out.

DR. LIANG: How about "Thorough handwashing is essential to prevent transmission of foodborne disease by infected food workers"? And in addition minimizes cross-

contamination or something like that. I mean just that handwashing--

DR. BUCHANAN: How about "helps control"?

DR. LIANG: What?

DR. BUCHANAN: "Helps control."

DR. LIANG: Yeah. Right. "In addition helps control cross-contamination."

DR. POTTER: Katy?

DR. SWANSON: The original thought of the sentence was handwashing prevents critters from getting into food that come from people and from other sources.

DR. POTTER: Okay. Okay. So what Art says will accomplish, I think, Katy's point. Thorough handwashing is essential to prevent transmission of--how did you say it, Art?

DR. LIANG: I left that sentence alone.

DR. POTTER: Okay.

DR. LIANG: That one talks about the human--

DR. POTTER: Okay.

DR. LIANG: --part of it and then the second sentence just focus on the--

DR. POTTER: Okay. In addition, handwashing minimizes the potential for cross-contamination from other sources?

DR. NAGLE: We don't have human there anymore. we have foodborne everywhere now.

DR. LIANG: The other sentence says from infected workers.

DR. POTTER: From infected food workers, though, is i the first sentence.

DR. BUCHANAN: Really then you can reduce that third sentence simply to "In addition, handwashing helps control cross-contamination from other sources."

DR. POTTER: Okay. "In addition, handwashing helps control," and then delete down to "cross-contamination." "In addition, handwashing helps control cross-contamination from other sources." I see nods. I see looks of absolute bliss.

[Laughter.]

DR. POTTER: All right. I've had a couple of suggestions that some people are getting a little desperate. Do we want to forge ahead because desperation aids consensus building?

[Chorus of yeses.]

DR. POTTER: Or do people want to take a break?

PARTICIPANT: Forge ahead.

DR. POTTER: Forge ahead.

PARTICIPANT: Full steam.

DR. POTTER: Full speed. Okay. Okay.

"Minimizing bare-hand contact of food provides a third method to interrupt disease transmission by infected individuals." Anybody want to change that sentence?

DR. BUCHANAN: I think you would provide a better rationale to relate it back to the sentence before where you're indicating that handwashing by itself is not totally adequate.

DR. POTTER: Okay. So do we need a new lead-in sentence? "Handwashing by itself" or "handwashing and exclusion/restriction by themselves"--what's?

DR. LIANG: Show me the data.

PARTICIPANT: Do we have the data that says that?

DR. POTTER: Okay. No data.

DR. BUCHANAN: You can no longer use the word "third method" because you eliminated the second method back earlier. So now you've got to get rid of "the third method."

DR. POTTER: Well, it just says it provides an additional--

PARTICIPANT: An additional method.

DR. BUCHANAN: Yeah.

DR. POTTER: Change "third" to "additional"?

DR. FARRAR: Using method or barrier?

DR. BUCHANAN: Means.

DR. POTTER: Means. Okay. "Means of"

PARTICIPANT: Of interrupting.

DR. POTTER: Of interrupting. Okay.

DR. SWAMINATHAN: You need to make that a little bit stronger.

DR. POTTER: Okay. Strengthen the sentence. Minimizing bare-hand contact of food provides an important, a critical, what words are you suggesting, Swami?

DR. BUCHANAN: And where is your data?

DR. POTTER: Okay. Do we want to change "an additional" to something else? Okay. Let's--

PARTICIPANT: Let's come back to it later.

DR. POTTER: Let's come back to it. Okay. "An additional means of interrupting" to "interrupt."

PARTICIPANT: You have to get rid of the "to interrupt."

DR. POTTER: Of interrupting. Of interrupting. Nodding heads. Of interrupting disease transmission by ill food workers or infected individuals?

PARTICIPANT: Ill food workers.

DR. BUCHANAN: Well, do we want to use--

PARTICIPANT: By definition.

DR. POTTER: Okay. All of this goes back to the definition of ill that's in the code. This technique, however, is not effective--now is "effective" the word or do we want sufficient?

PARTICIPANT: Sufficient.

DR. KVENBERG: Chairman, can I on the same sentence, to an earlier point?

DR. POTTER: John.

DR. KVENBERG: Yeah, the "Minimizing bare-hand," there's two issues. Minimizing--the charge was, number one, that we came in with, we basically didn't--being polite, we said we didn't really address the question that was asked in that the words used in the charge was "blanket prohibition." That's not addressed. It says "minimize." The second point is I guess you have it in there--ready-to-eat foods is now in there. But it gives me pause to say did we evade the charge by just starting the paragraph off with "Minimizing"?

DR. POTTER: Okay. But I got the sense from the earlier discussion today that that's as far as the committee felt the scientific data supported.

DR. KVENBERG: I totally agree with it. I just think the way it's responded to is a non-answer because--

DR. POTTER: Okay. How do we want to address John's issue. Jim.

DR. DICKSON: I guess I would offer an alternate on that. Obviously, if the committee felt that a blanket ban on bare-hand contact was in order, we would say that and we don't. We're saying minimize.

DR. KVENBERG: So as it is it's implicit.

DR. DICKSON: We're saying minimizing as opposed to making a statement about we endorse a blanket ban on bare-hand contact. So I don't know. To me it seems like we address the issue.

DR. POTTER: Mike.

DR. DOYLE: Couldn't we say that present science is not sufficient to support a blanket prohibition against bare-hand contact with ready-to-eat foods? However, minimizing bare-hand--

DR. POTTER: Katy?

DR. SWANSON: A slight twist on that. It might be more powerful to say that you should try to minimize but a blanket prohibition is not supported by data as opposed to the other way around because I think we do need to encourage minimizing hand contact willy-nilly.

DR. POTTER: Nancy?

DR. NAGLE: No, no, I was pointing out something.

DR. POTTER: Okay. All right. How do people want to react to Katy's modification of Mike's intervention?

DR. GROVES: I think Mike's intervention or statement, you know, is more direct. It's easier for me to understand and track.

DR. SEWARD: I like Mike.

DR. BUCHANAN: I'd argue that I prefer Katy's, that it puts up front the public health concern, but then says that we just were insufficient data to make a final decision.

DR. POTTER: All right. Mike Groves and Skip. Okay. How do you respond to Bob Buchanan's reaction to your statement? You're going to beat them up later. Stephanie.

DR. DOORES: I'm afraid that if we say that there's insufficient data to make that kind of statement, that gives too much wiggle room that it could lead people to disregard that because they're saying, oh, well, there's not enough data.

DR. POTTER: Okay. So what you're suggesting--

DR. DOORES: I'm not sure we want to go that far.

DR. POTTER: So would you just leave the sentence as it is, "Minimizing is an additional means," and just not qualify that? Nancy?

DR. NAGLE: No. I think to answer the question again, we have to come back to we were asked about a blanket prohibition and I think we have to address that and say, you

know, we all believe that minimizing the contact is important, but we did not see data that would totally support a blanket prohibition, and--

DR. POTTER: Okay. So Art will correct sentence structure, but can you start the paragraph then, "While the committee didn't see adequate data to support a blanket ban, minimizing bare-hand contact provides"--does that--Peggy?

DR. NEILL: I'm wondering if vis-a-vis Cathy's point, if you were to add at the end of the sentence "at the present time"? In other words, you're saying the committee didn't see enough data to support a blanket prohibition at this time.

DR. POTTER: Alison?

DR. O'BRIEN: Well, I'm going to disagree and I guess I'll be "n equals 1," because I saw enough data from the statements about New York and Massachusetts to make me say that you got to show me otherwise. So I mean I'll be an "n equals 1." I'll be the only one in disagreement. I just won't be part of a committee in making the general statement because you're making a consensus statement; right? I'm "n equals 1" of not agreeing.

DR. POTTER: Okay.

DR. DOORES: Maybe change "adequate data" to "compelling data." In other words, we saw data that led us

to think that maybe there was something there, but not sufficient to go that extra mile. So maybe compelling data.

PARTICIPANT: What is compelling?

DR. POTTER: Okay. We can also say that there was not unanimity of opinion on a blanket ban on bare-hand contact, but the committee did agree that the data supported minimizing. Does that suit folks? Okay. I see some nods. Go ahead and start that paragraph. Unanimity of opinion is not achieved on a total ban. Okay. There was no consensus. It's easier to spell. No consensus to support--

DR. SEWARD: Isn't it a consensus? Or I mean to me, if you're saying that if one person on the committee has an opinion that they express which is different from others, that any time there's a report that comes out, that the committee would then say although there was not a consensus on this--

DR. POTTER: Okay. So you would--

DR. SEWARD: Setting a precedent for--

DR. POTTER: You would go back to unanimity of opinion?

DR. SEWARD: Well, I don't even see why you need to say that unless--I mean myself personally I don't see why you need to say that. As we work through these different issues, I think there is always going to be people who don't

necessarily agree with the entire group, but I'm just wondering if you establish something where you're going to making--

CHAIRPERSON WACHSMUTH: Well, in the past, when we've had issues that are this important--I mean we have a lot of minor issues that have disagreement, but when it's something that may be this important, we can have a minority opinion. We can have a minority sentence or statement which could, you know, follow these two paragraphs. One or several members of the committee felt that the data indicated something.

DR. SEWARD: Okay. Thank you for clarifying that.

DR. POTTER: Okay. How would the committee like to say that? Jim?

DR. DICKSON: Morrie, I'd like to support the inclusion of a sentence relating to the minority opinion on this. That is that we have a minority opinion that there was sufficient data to support a blanket ban on bare-hand contact of ready-to-eat foods. I don't want to phrase Alison's sentence for her, but I think that's what she's saying. And I think that should be included in there.

DR. POTTER: Okay. A sentence or independent clause or--how would we like to say this?

DR. SWANSON: How did we do it for the HACCP document?

DR. POTTER: Uh?

DR. SWANSON: How did we do it for the HACCP document because there was more than one there? Do you remember?

DR. POTTER: I think in the HACCP document there were--

PARTICIPANT: No one ever formally--

PARTICIPANT: Written comments.

DR. SWANSON: Written comments. Okay.

DR. POTTER: Okay. Art.

DR. LIANG: I'm not on the procedure. I'm just suggesting we finish this paragraph and then take the paragraph that currently starts off anecdotal information and turn that into a minority statement. That's your call, Mr. Chair.

DR. POTTER: Okay. Art has suggested using the current paragraph, the current following paragraph, "Anecdotal information suggests"--"may have reduced foodborne illness" into a--rather than an anecdotal information--into a minority opinion.

DR. POTTER: Okay. Where do we put that? Do we add it to the end of this? Mike?

DR. GROVES: Morrie, wouldn't it be more accurate to say one committee member disagreed?

DR. LIANG: No, there's more than one.

DR. POTTER: Without going on, I would rather not put numbers unless we--

CHAIRPERSON WACHSMUTH: We hear that it's more than one. It's much better to avoid a vote if we don't have to do that.

DR. POTTER: Yes.

DR. O'BRIEN: But I think to expedite, why don't you finish writing it the way the majority feel that it should be written.

DR. POTTER: Okay.

DR. O'BRIEN: And then we'll state something. Otherwise we will be here till dinner.

DR. POTTER: Okay.

MR. BERNARD: That would be my suggestion. The chair had suggested earlier that we have some kind of a statement in here endorsing at least minimizing bare-hand contact, which we don't have right at the moment, and I think that is, at least my opinion that we have a second sentence that essentially does that. Something that says to the effect that information presented to the committee, however, does support minimizing bare-hand contact as an

essential component of a control program or something to that effect. I haven't worked out any words.

DR. POTTER: Well, but the first sentence kind of says that. If we change the second sentence to most committee members did not believe that sufficient data to support a blanket prohibition were presented. Peggy or Stephanie?

DR. DOORES: Can't you say that for the second sentence that it was not provided with sufficient or compelling data to support the prohibition, but that the committee does feel that minimizing it? In other words, for a blanket--we're not supporting a blanket, but we do feel that it should be minimized.

DR. POTTER: Again, we were trying to get at this issue of the divergence of opinion that exists. We all agree that minimizing it is supported by science. Some feel that the data support a blanket prohibition, but that's not the majority opinion, and I think that that's--Bob?

DR. BUCHANAN: Yeah, I was going--the National Advisory Committee, et cetera, et cetera, concludes that minimizing bare-hand contact of ready-to-eat food provides an additional effective means for interrupting disease transmission. However--start a new sentence, LeeAnne.

However, most members of the committee deemed the available scientific data insufficient to--and then the rest--

DR. POTTER: To support a blanket--

DR. BUCHANAN: --a blanket--

PARTICIPANT: We want "blanket" in front of "prohibition" because that was the key term.

DR. POTTER: That was the words in the charge.  
Okay.

MR. EKLUND: Morrie.

DR. POTTER: Mel.

MR. EKLUND: I would suggest on the first sentence there if you add a sentence by saying "interrupting disease transmission." We don't want ill workers there to begin with. And so the question--I think you would be better off just end with transmission, period.

DR. POTTER: All right. I see agreement on that.  
Okay. However, most members of the committee deemed the available scientific data insufficient to support a blanket prohibition of bare-hand contact with ready-to-eat foods.  
Alison, does this get at your minority opinion?

DR. O'BRIEN: Well, you've changed it because number three originally was the issue was related to ill workers. That's what the data I heard about New York was that worker associated foodborne outbreaks had not occurred

when--at least to the knowledge of the New York public health department--had not occurred when they were following the guidelines of no bare hands. So now we've just got it a more generic statement which is not quite the same thing.

DR. POTTER: Okay. What's the sense of the committee? Leave it in? Take it out?

DR. O'BRIEN: We've been focusing on ill workers in the other two paragraphs.

DR. POTTER: Ill by the definition of the code? Yeah.

DR. GROVES: We have to go back to the original question. And it's not just ill workers. I mean I think can transmission of foodborne illnesses via bare-hand contact with ready-to-eat foods be interrupted, and we said yes.

DR. O'BRIEN: Well, if we're going to change the question, then I have to change what I'm saying because now we're changing the question from what we were talking about before. We focused on food handlers.

DR. POTTER: I thought earlier we made a decision to restrict our answers to the conditions of workers because that was where data were presented. So it was my impression that this whole statement was focused on things transmitted from food workers so--Jim?

DR. ANDERS: I have a question about the word "insufficient." What are we saying here? Are we saying that there isn't any data because I don't agree with that? I mean I think there's not any compelling data, but if we're saying, if we're essentially trying to say that there isn't any data to support this at all, I don't agree with that.

DR. POTTER: Well, but it's insufficient to support a blanket prohibition. We've already agreed that the data support minimizing.

DR. LIANG: It doesn't say there are no data. It just says there are insufficient data.

DR. POTTER: Swami.

DR. SWAMINATHAN: I would suggest a small modification. How about after "minimizing" " where possible eliminating"?

DR. POTTER: As a parenthetical expression?

DR. SWAMINATHAN: Yes.

DR. POTTER: NACMCF concludes that minimizing parentheses--okay--once more, Swami. Just read the sentence as you think it should be written.

DR. SWAMINATHAN: "The NACMCF concludes that minimizing, and where possible eliminating, bare-hand contact."

DR. POTTER: Do the data talk to the possibility of eliminating? Alison?

DR. O'BRIEN: As far as I could hear the New York data were eliminating because the ruling is no bare-hand contact.

DR. POTTER: Right. But my question is did you hear data on whether eliminating was possible or not? I think as it's written now, the statement is--

DR. O'BRIEN: Well, I don't know. I assume that by enforcing the law--now I'm confused. The point was to eliminate. Whether it actually happened is a different story.

DR. POTTER: Right. Okay.

DR. O'BRIEN: In fact, I heard no data about the results of a policy that said let's try to eliminate or let's reduce. I never heard any data that said that was effective.

DR. POTTER: Right. And I guess that's what I think the sentence says.

DR. SWAMINATHAN: Okay. I withdraw my change.

DR. POTTER: Okay. How are we on the first two sentences in this paragraph? Can we go to the third sentence?

PARTICIPANT: Yes, move on.

DR. POTTER: I hear move on. "This technique, however"--that sentence, how do we want to say that?

DR. BUCHANAN: I think you're going to need a transition. "NACMCF also noted that this technique in the absence of ill worker exclusion/restriction and adequate handwashing"--

DR. POTTER: And "adequate handwashing."

MR. SPERBER: It was "the exclusion/restriction of ill workers."

DR. BUCHANAN: "Of ill workers," yeah.

DR. POTTER: And "adequate."

DR. BUCHANAN: "Adequate." "--is not sufficient to prevent transmission of human borne disease," period.

DR. POTTER: I thought that period would never come. Okay. Nancy?

DR. NAGLE: What data are you basing that statement on that we saw?

DR. POTTER: Okay. As the charter of the advisory committee and the charge stated, the committee members can also use information they carry with them in addition to the information presented. But it should be data driven, not opinion or folklore. I guess it can still be opinion, but it needs to be opinion supported by data.

DR. NAGLE: Bob, are you dead?

DR. BUCHANAN: Oh, I'm sorry, Nancy.

[Laughter.]

DR. POTTER: Not yet.

DR. BUCHANAN: We heard a series of experts talk about gloves, particularly in the surgical environment, and they all reinforced the fact that the thing you have to start off with first is washing your hands well. I would assume that this also, and this is my basic assumption, is that you would--even if you had done that, if you have someone that is really grossly ill, you would want to avoid their presence in the food preparation environment.

DR. NAGLE: But that's not what you just said.

DR. BUCHANAN: Yes, it is.

DR. NAGLE: You just excluding the guy and washing your hands isn't enough and--

DR. BUCHANAN: No. It says this technique referring to gloving or minimization of bare-hand contact by itself is not sufficient. That you have to do the other two steps.

DR. NAGLE: Oh, is that what you're trying to say.

MR. BERNARD: I would submit there are a lot more things we have to do to prevent foodborne illness including preventing cross-contamination which we referred to. I would prefer to take out the other two things in there and

leave it as a blanket statement that says it's not sufficient alone.

DR. POTTER: That actually gets out the question in the charge of singly or in combination.

MR. BERNARD: Right. So, LeeAnne take out everything between the two commas.

DR. LIANG: I like Dane's suggestion.

DR. POTTER: Okay. Thanks, Art.

PARTICIPANT: Can we clarify "this technique," please?

DR. POTTER: Okay. So "NACMCF also noted that avoidance of bare-hand contact"?

MR. BERNARD: Uh-huh. I think we need to add "alone."

PARTICIPANT: "Alone."

MR. BERNARD: After "sufficient."

PARTICIPANT: Or avoidance of bare-hand contact.

MR. BERNARD: Avoidance of bare-hand contact alone.

DR. LIANG: Foodborne disease is awkward.

DR. KVENBERG: Yeah.

DR. POTTER: John?

DR. KVENBERG: Two of us instantly reached the same thing. It's rather awkward within that sentence to say

is sufficient to prevent transmission of human borne disease.

DR. POTTER: We're talking about things that-- we're talking specifically about agents that are coming to the environment in the--

DR. KVENBERG: Via the fecal-oral root.

DR. POTTER: Right.

DR. BUCHANAN: From humans.

DR. POTTER: From humans. So it's human origin pathogens that are foodborne, that cause foodborne disease. I mean there's a very long and awkward sentence in the ADA about that.

DR. LIANG: How about "not sufficient to prevent disease transmission," period?

DR. POTTER: Okay. Art is suggesting that if we end the sentence "not sufficient to prevent transmission"--

DR. LIANG: "Disease transmission."

DR. POTTER: "Not sufficient to prevent disease transmission," by reference to the entire document, readers will know what the word "disease"--Peggy?

DR. NEILL: I was going to suggest--I think trying to follow up on Bob's direction with the sentence is I thought what we're after saying is avoidance of bare-hand contact cannot supplant the other strategies.

DR. POTTER: Okay. How does the committee feel about that? Committee is going into hypoglycemia.

[Laughter.]

DR. KVENBERG: An alternative?

DR. POTTER: Johnny?

DR. KVENBERG: An alternative would be just use the word "direct" after "prevent." Hand contact alone is not sufficient to prevent direct transmission of foodborne illness. I mean the concept is fecal-oral and isn't that the point of the sentence? Is that what you're trying to say? Direct transmission from the worker?

DR. POTTER: Does the committee feel that John's intervention addresses Peggy's concept? Peggy does not. Okay. Let's suggest some words. Swami.

DR. SWAMINATHAN: The word "additional" in the third line of that paragraph means exactly what we've been struggling to say in that sentence. I would just strike out that sentence.

DR. POTTER: Okay. The first sentence reads "NACMCF concludes that minimizing bare-hand contact of ready-to-eat foods provides an additional means." I think the only distinction there, Swami, is that as stated that could be a single method or a method in combination with the

other two. And I think that what this sentence is trying to address is that it's not a stand alone. Alison?

DR. O'BRIEN: Why don't you just say provide--I'm sorry--"provides an additional means, in combination with"--blank, blank--"of interrupting disease transmission"?

DR. POTTER: Swami agrees. I have two people who like that.

DR. O'BRIEN: That's the issue.

DR. POTTER: Anybody else buying? Anybody who can't stand it? I mean anybody who doesn't like it? Okay. Go ahead and make that?

MS. JACKSON: What is it you want me to say?

DR. POTTER: Okay. "An additional means,"--Alison?

DR. O'BRIEN: "In combination with"--what did we say--

DR. POTTER: "In combination with"--

DR. O'BRIEN: I said blank, blank because I wanted to use the same words--

DR. POTTER: Yes.

DR. O'BRIEN: --with "exclusion/restriction of infected workers and a thorough handwashing,"'

DR. POTTER: ",of interrupting disease transmission." Then the "however" sentence and then we

eliminate the sentence that starts "NACMCF also noted that"-  
-everyone agree to eliminate that sentence now? John?

DR. KVENBERG: Could we just insert instead of  
"thorough" because that's difficult to define--use the word  
"proper" which I think is code language so they understand.  
It's spelled out in the code what's proper. It's minor,  
but--

DR. POTTER: Okay. Anybody object to--

DR. O'BRIEN: Just that you need to put proper in  
the preceding paragraph if you put it there; don't you?

DR. POTTER: Okay. We can--

DR. KVENBERG: Yeah, I caught that.

DR. POTTER: Okay. Okay. Now go back to where we  
were.

DR. BUCHANAN: My recommendation is that after the  
sentence, the second sentence, that you just eliminate  
everything else.

DR. SWAMINATHAN: I agree.

DR. POTTER: Okay. So now we're going to--it's  
been suggested to go down to the line "bare-hand contact  
with ready-to-eat foods and eliminate everything else for  
the rest of the paragraph?

[Chorus of "rights."']

DR. POTTER: Second? Anybody object to eliminating the highlighted areas of that paragraph? Gone. All right. Anecdotal information. Is that now covered adequately, Alison?

DR. O'BRIEN: Yes.

DR. POTTER: Okay. Do we need this paragraph? Who wants to keep the highlighted paragraph? Gone. Okay. Highlight the next paragraph. Who wants to keep this paragraph? Stephanie?

DR. DOORES: I think we should have something at the end about education.

DR. POTTER: Okay. But this highlighted--

DR. DOORES: But not necessarily the first sentence, but implementation of--keep that last sentence there.

DR. POTTER: Okay. Okay. So LeeAnne, just highlight the first sentence in that paragraph. Okay. John?

DR. KVENBERG: I don't disagree with Dr. Doores' desire to keep it, but I will pick on what that sentence says, that education--I don't believe it's true. We haven't got evidence to say that it's true. I mean it's really saying education is good, but being--it goes too far by saying more effective than bare-hand contact prohibition

policy. That was a judgment we never discussed or--it should be recrafted as a sentence if we're going to retain education.

DR. POTTER: Okay. Let's talk first about the highlighted sentence. Do we want to keep this in or cut it?

PARTICIPANT: Cut it.

PARTICIPANT: I don't think we know.

PARTICIPANT: Cut it.

DR. POTTER: Cut it. Okay. Now, the next sentence here--

DR. BUCHANAN: I would recommend that this sentence be eliminated and we move down to restructuring the sentences that we moved from earlier in the document which are more on point.

PARTICIPANT: Yeah, second that.

PARTICIPANT: I agree.

PARTICIPANT: Yes.

DR. POTTER: Okay. Highlight that sentence, LeeAnne. Do we want to keep it or cut it?

[Chorus of "cut's.]

DR. POTTER: Cut. All right. Okay. Now--

DR. BUCHANAN: And these are the sentences we want to modify and I think the focus should be here is on implementation.

DR. POTTER: Okay. So, Bob, if I understand what you're saying correctly is implementation of these three measures?

DR. BUCHANAN: Implementation of the three intervention strategies that we've outlined above are going to require both education and commitment on the part of the industry and all affected by it.

PARTICIPANT: Did we hear any--

DR. POTTER: Well, we certainly--people said that in their presentations. Now is that the same as--or do we know from other activities we have that as a matter of behavioral science that this is a true statement?

DR. BUCHANAN: Just, if nothing else, Morrie, I don't think of in it's ten year history there has not been a single recommendation coming out of this that did not recommend either an education component or a research component.

PARTICIPANT: More, more, more.

DR. POTTER: Okay.

DR. BUCHANAN: So if nothing else, by precedent--

DR. POTTER: Okay. Implementation of the three intervention strategies outlined above will require and then cut to education and let's see how it looks.

PARTICIPANT: That was good.

DR. BUCHANAN: Very small.

DR. POTTER: It looks small.

[Laughter.]

DR. POTTER: Okay. "Implementation of the three intervention strategies outlined above will require education of food handlers." We're going to change that to workers. And folks from the industry want to say--are those the right populations? "Food workers and food management to ensure." Okay. Everyone--

MR. SPERBER: Food workers and managers.

DR. POTTER: Food workers and managers. So eliminate "and food." Or food workers and managers. Right. To ensure that. Okay. People like that paragraph?

DR. BUCHANAN: That's fine.

DR. POTTER: I hear one vote.

PARTICIPANT: Sounds good.

DR. POTTER: Okay. Multiple votes. The stuff that LeeAnne just put in parentheses is for consistency with the rest. Ill food workers?

PARTICIPANT: Right.

DR. POTTER: Okay. Now having said that, do we also need again education, that paragraph? Dane, you had something?

MR. BERNARD: Well, as everybody knows, I am easily confused, but the last part of what we just modified now brings up one of the three components and links it with education. So I worry that maybe we've included too much or we're going to have to include more.

DR. POTTER: Okay. What's your proposed fix?

MR. BERNARD: That illness can be transmitted through food contamination, full stop.

PARTICIPANT: That's right.

DR. POTTER: Okay. Do we have agreement to end the document there?

PARTICIPANT: Second that.

DR. POTTER: Anybody? Oops. Okay.

DR. SWANSON: No.

DR. POTTER: Katy, Peggy, you can speak in unison if you'd like.

MR. BERNARD: Together with harmony.

[Laughter.]

DR. NEILL: Actually when I had done this before had deleted the illness through--illness transmission through food contamination because that's generic. The point of this document had to do with answering questions about bare-hand contact. So consequently you are trying to say that--food workers and managers are educated to ensure

they understand the consequences of food preparation by ill individuals.

MR. BERNARD: But it's not only ill.

DR. POTTER: Well, by the definition in the code that includes--

DR. NEILL: Infected or what--I mean in the context of the charge, we're not dealing with all foodborne illness.

DR. POTTER: Okay.

MR. BERNARD: Let me suggest then, as I said, we've either gone a little bit too far or we haven't gone far enough, that the education be linked with the effectiveness of the interventions that we've outlined and that focuses--you've got ill workers, transmission to food. Here are the things that should be done in this context.

DR. POTTER: Okay. Dane, are you suggesting that maybe we should perhaps think of ending the sentence after the word "understand"?

DR. BUCHANAN: Can I make an alternate suggestion?

DR. POTTER: Yes.

DR. BUCHANAN: That the sentence read "Implementation of the three intervention strategies outlined above will require education of food workers and

managers to ensure that they understand their role in preventing the transmission of foodborne disease."

[Chorus of affirmation.]

DR. POTTER: All right. I hear some people who like that and see Peggy shaking her head no.

DR. NEILL: I was just going to say I think we want them to understand these points. I mean that's too simplistic, but--

PARTICIPANT: To understand these points?

DR. NEILL: These strategies for control.

DR. POTTER: Art.

DR. LIANG: You guys are going to get angry at me for this, but I think social change is not always and educational strategy and education isn't always a social training strategy. You know physicians have some of the worst compliance when it comes to their own treatment and they know-presumably know the most. So I really think this--that's why I think this education thing is being oversold by everybody. Sorry.

DR. POTTER: So education and motivation?

MR. BERNARD: So what's your point, Art?

DR. POTTER: Katy?

DR. SWANSON: The original intent of the sentence was to point out that some of these people who aren't

educated don't know that if they're sick, they can transmit that disease through food.

DR. POTTER: Okay. Do we want--does the committee want to restrict this sentence to that concept? Just teaching people that if they're sick, they can transmit their disease? Johnny?

DR. KVENBERG: Regulator that I am, I think not yet.

DR. POTTER: Johnny disagrees.

DR. KVENBERG: The hidden meaning in that is you need enforcement in addition to education to make it work.

MR. BERNARD: Well, do you want there "role and responsibilities"?

DR. KVENBERG: No. I guess what I'm saying is the implementation of three intervention strategies does require education and training of the food workers and managers. That's a true statement. The second part that Dr. Liang did insert is behavior modification may require more than education. I'm agreeing with his statement.

DR. POTTER: Do we stop there?

DR. KVENBERG: Stop. I think the implementation of these intervention strategies requires enforcement.

DR. POTTER: Jim?

DR. DICKSON: My comment was that three of the components here are education, management commitment and also enforcement by state and local regulators. We were talking specifically about implementing these three strategies.

DR. BUCHANAN: We're heading into policy country.

DR. DICKSON: We're talking about implementing three strategies to prevent foodborne disease.

DR. POTTER: Jim.

DR. ANDERS: Yes. If we're trying to say here that education is going to solve this,--I guess someone else mentioned this--it may not do it. We spent millions of dollars trying to educate people with AIDS that they could transmit the disease and actually the rates now of using protection has actually decreased considerably after millions and millions of dollars. So I guess I don't have any problem with putting in something about education, but if we're implying that that's going to necessarily make any difference, I'm not so sure that we can conclude that.

DR. POTTER: Bill.

MR. SPERBER: I have one suggestion. We could say for that first sentence: "Implementation of the three intervention strategies outlined above will require training

and motivation of food workers and managers," period.  
Strike everything else.

DR. POTTER: Okay. There's a proposal on the  
table. We have any discussion of Bill's intervention?

DR. BUCHANAN: Where would it stop?

MR. SPERBER: After "managers." --"will require  
training and motivation." Education and training are the  
same thing, but we'll say training for the industry. Take  
off the parentheses.

DR. POTTER: Perhaps in some quarters, "education"  
would be more a acceptable word than "training."

MR. SPERBER: Well, one or the other is fine. I  
don't see the need for both.

DR. POTTER: Right.

MR. SPERBER: They are synonymous.

DR. POTTER: Why don't we say--

MR. SPERBER: Education and motivation.

DR. POTTER: Some people think that some people  
shouldn't be trained but rather educated.

MR. SPERBER: Okay.

DR. POTTER: "Education and motivation of food  
workers and managers." Okay. So this would be a statement  
based on behavioral science. Is that everyone's  
understanding?

PARTICIPANT: Right.

DR. POTTER: Okay. Does the group want to end the statement after the word "managers"?

PARTICIPANT: Sounds good.

DR. POTTER: Anybody want to keep the rest of the paragraph?

[Chorus of noes.]

DR. POTTER: Anybody want to keep the paragraph below it if there is still one below it?

[Chorus of noes.]

DR. POTTER: Okay. Is that the rest of the document?

PARTICIPANT: That's it.

DR. POTTER: Okay. Bob?

DR. BUCHANAN: Going back to our usual MO, considering the severe data gaps that we experienced in coming to this document here, I wonder if there should not be a statement about the state of information related to this issue?

DR. POTTER: Okay. Jeff brought up that point before saying that this committee had an obligation to identify either the data gaps or stopped being short of that, identify that data gaps existed. Can we put that into this paragraph? Implementation of three intervention

strategies outlined above will require education and motivation of food workers and managers. Additional data--

PARTICIPANT: Additional research is needed.

DR. POTTER: Additional research or additional data are needed to--will be needed to make stronger recommendations? I don't know where we're going with this. Jeff, you brought it first. It's your fault.

DR. FARRAR: Sorry. It seems to me the data focuses specifically on blanket prohibition of bare-hand contact. So the sentence on additional needs, research needs or data, should include that caveat.

DR. POTTER: Well, Jeff, again the original question talked about or addressed issues other than infected food workers. It addressed issues other than gloves. Do we want to say that to fully respond to the questions? Bob?

DR. BUCHANAN: I think--and maybe it's because I'm getting hungry--I'm not sure at this point that we need to go into a long list of specific areas where research is needed. That I think we should just simply acknowledge that severe data gaps were identified during the committee's deliberation and that the committee recommends that the appropriate federal agencies seek to correct that situation.

DR. POTTER: John.

DR. KVENBERG: This is only to bring it to closure, but a crisp end would be since reading the charge one more time, the key phrase is bare-hand contact, so would it be appropriate in the area of additional research is needed getting back to the charge of the question that was asked on bare-hand contact? That seems to be the core issue of the question that was asked. And that's the honest answer where you would like to have, I think, additional research needs where the gaps were.

DR. POTTER: So additional research is needed on the public health consequences of bare-hand contact with ready-to-eat foods.

DR. O'BRIEN: This is a circular argument because how do you get the data unless you have, can make some kind of comparison in a public health environment of bare-hand contact prohibition versus non-prohibition? And the only data we're getting is from New York, but I gather there is no other state we can get that information from?

DR. POTTER: FoodNet is going to try to address some of those issues by doing a restaurant-based case control study using outbreak related or outbreak associated restaurants versus a comparison restaurant, not outbreak associated. Okay. "Additional research is needed on the public health consequences of bare-hand contact with ready-

vsm

to-eat foods." Okay. End of discussion? I mean end of--  
then can everything else be eliminated?

Okay. We will have this printed and circulated so  
that Friday we can--

CHAIRPERSON WACHSMUTH: We can bring it up again.  
What would be nice is if we could get a copy to everyone  
tonight or tomorrow morning and try to keep your changes to  
editorial ones since we've gone through a rather  
excruciating discussion. And then we'll sort of give it the  
nod on Friday before we adjourn. Good job. Have a nice  
afternoon.

[Whereupon, at 1:35 p.m., the committee recessed,  
to reconvene at 8:05 a.m., Thursday, September 23, 1999.]

- - -