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FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

NATIONAL ADVISORY COMMITTEE

ON

MICROBIOLOGICAL CRITERIA FOR FOODS

VOLUME I

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WELCOME AND INTRODUCTION

CHAIRPERSON WACHSMUTH: I think we need to begin. We have a pretty full day. I'd like to welcome everyone this morning.

Good morning this bright, sunny day in Washington. I want to welcome everyone and really tell you how much we appreciate your coming. I know this is a very busy time of year for everyone, school time, government time, probably industry time, so your time is valuable and we realize that and we are going to try to pack this meeting with only meaningful things.

I will also hold all of the business that we have for the committee with the committee until tomorrow morning. We have a few announcements and information for you and need some feedback from you on some different articles and some housekeeping issues, but I think that can all wait until tomorrow.

What I would like to do is just begin with David and have everyone introduce themselves, give your affiliation, and after we go around the room, I will turn the meeting over to Morry Potter, who will chair today's session. This is the "Bare-Hand Contact of Ready-to-Eat Foods at Retail." The next few days will also be committee

meetings, but these will be--the meeting tomorrow will be committee discussions. It is open to the public if the public wants to come and listen, but it is for the committee only to discuss. The following day, Thursday, we will have the Listeria monocytogenes risk assessment, and Friday, the Vibrio risk assessment, with a few other issues thrown in.

David, do you want to start?

DR. ACHESON: David Acheson, Tufts University and New England Medical Center.

DR. ANDERS: Jim Anders, North Dakota Department of Health Laboratories.

DR. BERNARD: Dane Bernard, National Food Processors Association.

DR. BUCHANAN: Bob Buchanan, FDA.

DR. DICKSON: Jim Dickson, Iowa State University.

DR. DONNELLY: Cathy Donnelly, University of Vermont.

DR. DOORES: Stephanie Doores, Penn State University.

DR. ENGELJOHN: Daniel Engeljohn, U.S. FDA's Food Safety Inspection Service.

DR. EKLUND: Mel Eklund, Mel Eklund and Associates in Seattle.

DR. FARRAR: Jeff Farrar, California Department of Health.

DR. JAHNCKE: Michael Jahncke, Virginia Tech.

DR. KOBAYASHI: John Kobayashi, Washington State Health Department.

DR. HULEBAK: Karen Hulebak, U.S. FDA, FSIS, Food Safety and Inspection Service.

CHAIRPERSON WACHSMUTH: Kaye Wachsmuth, Food Safety Inspection Service.

DR. POTTER: Morry Potter, FDA.

DR. JACKSON: LeeAnne Jackson, FDA.

DR. SEVERIN: Scott Severin, Department of Defense, Veterinary Service Activity.

DR. LIANG: Art Liang, CDC, Food Safety Initiative.

DR. KVENBERG: John Kvenberg, Food and Drug Administration.

DR. LONG: Earl Long, Centers for Disease Control.

DR. MORALES: Roberta Morales, Research Triangle Institute.

DR. O'BRIEN: Alison O'Brien, Uniformed Services, University of Health Sciences, Bethesda.

DR. NAGLE: Nancy Nagle, Nagle Resources.

DR. ROBACH: Mike Robach, County Group Companies.

DR. RUPLE: Angela Ruple, National Marine Fishery Service.

DR. SEWARD: Skip Seward, McDonald's Corporation.

DR. SPERBER: Bill Sperber, Cargill.

DR. SWAMINATHAN: Bala Swaminathan, CDC.

DR. SVEUM: Bill Sveum, Campbell Soup Company.

DR. SWANSON: Katie Swanson, the Pillsbury Company.

DR. GROVES: Mike Groves, LSU School of Veterinary Medicine.

CHAIRPERSON WACHSMUTH: Okay. Thank you all again. I'll now turn it over to Dr. Potter with FDA.

DR. POTTER: Thanks, Kaye. The session today will be devoted to a discussion of the public health implications of "Bare-Hand Contact of Ready-to-Eat Foods at Retail." I'd like to welcome the committee and observers today to this session. Thank you all for participating.

What I'd like to start with is to very briefly outline what is being asked of the committee so that you can have that in mind as you listen to the presentations that will follow today.

The National Advisory Committee is charged with providing scientific and technical advice to its sponsoring

agencies. We are supposed to in this committee focus on issues of science and technology, not on policy.

The issue currently before the committee is that of "Bare-Hand Contact of Ready-to-Eat Foods at Retail." The matter is being brought to the committee following discussions at the Conference for Food Protection in 1998. The food code provisions contained a blanket prohibition on bard-hand contact with ready-to-eat foods in retail food establishments and several objections were brought up to that provision of the food code in the 1998 conference. It was suggested in the conference that the question be brought to the committee so that the scientific merits of the questions could be reviewed.

The first question before the committee is, do you believe that bare-hand contact with ready-to-eat foods is a contributing factor in the transmission of foodborne illness? If so, can the transmission of foodborne illness via bare-hand contact with ready-to-eat foods be interrupted?

If you believe that it's possible to interrupt transmission, based on your prior knowledge and the scientific information and data presented during this meeting, please indicate which of the following three potential or possible interventions--one, the prohibition

against ill or infected workers from preparing food; two, hand washing and personal sanitation requirements; and three, prohibition of bare-hand contact with ready-to-eat foods--which of those three, individually or in combination, is likely to provide the maximum public health benefit in terms of reducing the incidence of foodborne illness.

So those are the questions that we would like addressed by the committee following the presentations. So with that and with a minute to spare, we can get started on the agenda.

Are there questions on the charge from the committee? Yes?

DR. BERNARD: Thank you, Dr. Potter. I think those questions are very clear, but for my information, how will the output from this session be taken before the--what is the next group to take those recommendations, the National Conference for Food Protection?

DR. POTTER: The next group to look at this will be the agencies themselves that will look at advice and recommendations from the committee and formulate agency positions to take to the conference, along with whatever written information comes out of the committee.

DR. BERNARD: Okay. So we are formulating a set of recommendations for the agency to then take a look at and then take forward to the National Conference?

DR. POTTER: Correct.

DR. BERNARD: Thank you.

DR. POTTER: Other questions?

[No response.]

DR. POTTER: Seeing none, let's go to the first section of the conference. I'd like Betty Harden from the Office of Field Programs in CFSAN to begin her presentation.

BACKGROUND OF THE ISSUE

MS. HARDEN: I trust this microphone is on. Good morning. I am pleased to introduce to the committee a synopsis of the background surrounding the issue of the day from the perspective of the FDA's model food code. Very simply stated, the issue is the fecal-to-oral transfer of foodborne pathogens by way of human hands from the feces of a food worker to the mouth of a consumer.

Although FDA has developed model codes for retail-level food establishments since 1934, the provisions of those codes related to fecal-oral transmission were general and subjective. For example, both the 1976 Food Service Sanitation Manual and the 1982 Retail Food Store Sanitation Code stated, "to avoid unnecessary manual contact with food,

suitable utensils, dispensing utensils, shall be used by employees."

Despite the fact that such model food code statements were widely adopted by jurisdictions throughout the United States, foodborne illnesses attributed to food worker contamination continued. It became apparent that viruses and low-infectious dose bacterial pathogens continued to hitchhike their way from hands soiled in the toilet room onto prepared foods.

Beginning with the 1993 food code, FDA sought to achieve a heightened level of consumer protection from such contamination by strengthening recommended public health policy related to the health of food employees and to hands as a vehicle of contamination. That enhancement involved added specificity and rigor through, one, detailed instructions for removing ill food workers from activities in which they could contaminate food; two, hand washing regimens for removing pathogenic organisms from hands; and three, interrupting the transfer of pathogens from hands to food by prohibiting bare-hand contact with ready-to-eat food.

Debate surrounding all three of these barriers promptly ensued release of the 1993 food code. Challenges, particularly from industry, to the bare-hand prohibition

continued through the 1998 Conference for Food Protection meting. My colleague, Mr. Tom Leitzke, past Conference Chair and current Chair of one of its three councils, will present information about the conference and its recommendations related to this issue.

The April 2, 1999, Federal Register notice set forth the recent history of the model code's bare-hand prohibition and posed a number of questions that reflect many of the concerns raised at the conference meeting in April of 1998. Those concerns, I anticipate, will be articulated by this morning's industry panel.

It should be noted that in response to industry's concerns about the practicality of an absolute prohibition in all situations, the 1999 food code does address a method of alternative compliance which includes a systematic approach to controlling the fecal-oral hazard.

I hope my comments have provided an adequate backdrop for the committee's entertaining of relevant information that all the stakeholders will bring to bear on the subject. It is with that information and your collective knowledge that we request your scientific review and advice. Thank you.

DR. POTTER: Thanks, Betty. Dr. Leitzke, if you'd like, you can either use the podium or the floor mike.

MR. LEITZKE: I think this will work fine. I do have to make one correction, my honorary degree. I am not a doctor.

Good morning. It is a real pleasure to be here to discuss the Conference for Food Protection and its relationship to bare-hand contact with ready-to-eat foods. As I said, my name is Tom Leitzke. I'm Director of Food Safety and Inspection in the State of Wisconsin, Department of Agriculture, Trade, and Consumer Protection, and the immediate past Chair of the Conference and I'm Chair of Council 3 for the conference in 2000.

The CFP, Conference for Food Protection, brings together a variety of opinions. It brings together academia, regulatory, food industry, and consumers to discuss and identify food safety issues. It has no regulatory authority. However, it does have powerful recommendations made to the agencies for inclusion in the food code.

The CFP has been interested in bare-hand contact with ready-to-eat foods since the 1993 food code was proposed by the Food and Drug Administration. As Betty mentioned, the discussion began immediately upon release of that document. We have deliberated it at conferences in 1994, 1996, and 1998.

In 1996, the conference recommended adding the phrase, "or when otherwise approved," to the food code in the section prohibiting bare-hand contact with ready-to-eat foods. This proposal was accepted by the Food and Drug Administration.

In 1998, the Conference on Food Protection requested clarification from the Food and Drug Administration as to what does "or whenever otherwise approved" and what are criteria that need to be met to ensure an adequate intervention to protect the public? FDA has provided clarification and guidance in an annex to the 1999 food code. It provided public health reasons for elimination of bare-hand contact and prevention with a variety of interventions and uses a HACCP concept to ensure that requests for incidental bare-hand contact can be managed in an appropriate manner.

Also in 1998, the reason we are here today, the CFP asked that FDA work with the National Advisory Committee to obtain your recommendations, based on science, as to what the effects of bare-hand contact of ready-to-eat foods are and what type of interventions would be useful and necessary, and we have asked that that be reported back to the conference in 2000 where we can again consider these

issues and move forward to a better control of this subject. Thank you.

DR. POTTER: Thanks, Tom. For the committee, we will take questions and comments for the first three speakers after this section is completed.

The next presenter is Mimi Sharar from FSIS. Mimi, use the podium, because the floor mikes are behind some of the committee members.

MS. SHARAR: Good morning. Dr. Dan Lazenby regrets that he can't be here today to give his presentation and he has asked me to give the presentation for today. It's a pleasure to speak this morning on behalf of the Food Safety Inspection Service, to offer my support of Food and Drug Administration's efforts to address the issue of bare-hand contact of ready-to-eat foods at retail.

FSIS is the agency within the U.S. Department of Agriculture responsible for ensuring the safety, wholesomeness, and accurate labeling of meat, poultry, and egg products. Our agency over the past five years has planned and is implementing a strategy for change that has as its goal reducing the risk of foodborne illness associated with meat and poultry products. Our strategy for change has been multi-faceted and broad, involving not only

federally-inspected establishments, but also the entire farm-to-table continuum.

The centerpiece of our strategy is the Pathogen Reduction and Hazard Analysis and Critical Control Point rule issued on July 25, 1996, or the PR-HACCP rule. This rule addresses the serious problem of foodborne illness in the United States associated with meat and poultry products by focusing more attention on the prevention and reduction of microbial pathogens in raw products that can cause illness. It also clarifies the roles of industry and government in food safety. Industry is responsible for producing safe food, while government is responsible for setting appropriate food safety standards, maintaining vigorous oversight to ensure those standards are met, and operating a strong enforcement program.

The pathogen reduction and HACCP rule has the following requirements. One, it requires all meat and poultry plants to develop and implement written standard operating procedures for sanitation. Two, it mandates that meat and poultry slaughter plants conduct microbial testing for generic E. coli to verify the adequacy of their process controls for the prevention of fecal contamination. Third, it requires all meat and poultry plants to develop and implement a system of preventive controls known as HACCP to

improve the safety of their products. And four, it sets pathogen reduction performance standards for salmonella that slaughter plants and plants producing raw ground products must meet.

These regulations that have been implemented over a three-year period focus on hazards within slaughter and processing plants. FSIS recognizes, however, that these measures must be part of a comprehensive food safety strategy that addresses hazards at other points in the farm-to-table chain. Thus, FSIS has broadened the scope of its food safety activities beyond slaughter and processing plants.

To improve safety of the animal production and intermediate stages before reaching the slaughter plant, FSIS is working with industry, academia, and other government agencies to develop and foster voluntary measures that can be taken on the farm and through distribution and marketing of animals to reduce food safety hazards. FSIS believes the voluntary application of a food safety quality assurance program based on HACCP principles can be useful in establishing risk reduction strategies and many industry groups are implementing such programs.

Food safety during transportation, storage, and retail sale are also important links in the food safety

chain. In these areas, FSIS, FDA, and State and local governments share authority for oversight of food products. FSIS and FDA are working together to develop standards governing the safety of foods during transportation and storage, and in the retail area, FSIS and FDA are working with State officials through the Conference for Food Protection to ensure the adoption of uniform science-based standards as part of the food code.

Even as progress is made in reducing contamination during stages, it will remain critical that retail food handlers and consumers follow safe food handling practices. FSIS has augmented its food handler education effort by expanding its collaboration with industry, other government agencies, consumer and public interest groups, educators, and the media to foster the effective delivery of food safety education and information.

In closing, we support and commend FDA and all of the contributors that assisted in the development of the white paper that is being presented to the Advisory Committee for its review and recommendations. The FSIS is extremely interested in the results of the review. Thank you.

DR. POTTER: Thanks, Mimi.

Does the committee have questions for Betty or Tom or Mimi? Anything that was brought up during this first session that you'd like clarification or amplification on? David?

DR. ACHESON: A couple of the speakers mentioned approved alternative methods. I mean, we may hear about these as this develops, but will that be covered later?

DR. POTTER: Betty, would you like to address that?

MS. HARDEN: The alternative methods for satisfactory compliance or approved alternatives were issued by FDA in the 1999 food code in response to what Tom Leitzke mentioned was the conference's request for interpretation, clarification of "or when otherwise approved" that was inserted in the food code's prohibition for bare-hand contact of ready-to-eat foods.

It is contained in the annex to the food code under public health reasons and administrative guidelines, and it basically applies a HACCP-based approach by saying that all the prerequisite requirements that pertain to fecal-oral transmission have to be in place, that there has to be a system of education and training, monitoring, surveillance, verification, and that the hazard has to be openly recognized, and that there has to be a validation

that there is no way that bare-hand contact can be eliminated. So it's a HACCP-based approach to analyzing the hazard and controlling it.

DR. ACHESON: Thank you.

DR. POTTER: Bob?

DR. BUCHANAN: Betty, could I follow up a question, just looking at the scope of what's been brought to the committee. You've indicated a focus on oral-fecal contamination. Are you equally interested in control of organisms of food safety concern that are not transmitted by oral-fecal route? In particular, I'm thinking of Staphylococcus aureus.

MS. HARDEN: Certainly, we are, and chapter two of the food code attempts to address that as well as other provisions throughout the food code, but I think the focus here is fecal-oral and breaking that chain.

DR. POTTER: Other questions?

[No response.]

DR. POTTER: Okay. Seeing none, we'll go on to the epidemiology section and the first speaker is Dr. Eileen Barker from CFSAN.

[Pause.]

DR. POTTER: I'd like to ask for the committee's patience here. I think one of those new technologies that

makes things better needs some time to get in place. As soon as the speaker is ready, we can go ahead.

[Pause.]

EPIDEMIOLOGY

DR. BARKER: Good morning. This will be a discussion of the foodborne disease outbreaks associated with food workers derived from a literature review covering the years 1975 to 1998. I would like to thank Dr. Marianne Ross for her preparation of the document and development of the survey. The next slide, please.

I will follow the following agenda with introduction, methods of data collection, foodborne outbreaks, discussion of limitations, and conclusion. Next slide, please.

Foodborne diseases are known to contribute to both human morbidity and mortality as well as to health care costs. The latest estimates from CDC indicate that there are 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths due to foodborne disease. These illnesses are 67 percent viral, 30 percent bacterial, and 3 percent parasitic. The information was published in the latest edition of the CDC publication, "Emerging Infectious Diseases." Estimates of the percentage of these illnesses attributed to food workers have ranged widely. Costs

include medical treatment costs, business losses, losses in productivity, in addition to the primary cost of controlling the disease. Next slide, please.

During the five-year period from 1988 to 1992, 2,434 outbreaks of foodborne disease were reported to CDC. One-thousand-four-hundred-and-thirty-five had information concerning contributing factors. Of these, the two most commonly reported practices were improper holding temperatures of foods in 59 percent and poor personal hygiene of food workers in 36 percent of outbreaks. Next slide, please.

Hand contact represents a potentially important mechanism for introducing pathogens into ready-to-eat foods by food workers. Next slide, please.

Food workers may transmit pathogens to food from a contaminated surface, from another food, or from hands contaminated with organisms from the gastrointestinal tract. Therefore, hand contact with ready-to-eat foods represents a potentially important mechanism by which pathogens may enter the food supply when ready-to-eat foods are defined as food that is edible without washing, cooking, or additional preparation by the consumer or the food establishment and is reasonably expected to be consumed in that manner. Next slide, please.

Six electronic databases were searched. These were Pop Med, Grateful Med, Educational Resources Information Center, Agricultural Online Access, Food Science Technology Abstracts, Biologic Abstracts, and the Centers for Disease Control and Prevention publication website. We looked at medical journals published in English for the period 1975 to 1998 for articles that described foodborne disease outbreaks believed to have resulted from the introduction of pathogens into food by food workers. Next slide, please.

Articles were included in the review provided that they described in sufficient detail the epidemiological or laboratory evidence to implicate a food worker as the source of infection. Next slide, please.

In order for an outbreak of foodborne disease to be classified as one resulting from the contamination of food by a food worker, we required that at least one of the following criteria be presented convincingly. The first criteria was sufficient epidemiologic evidence presented to link the food worker with the outbreak. Factors considered here included whether the period of time of the employee's contact with the implicated food was consistent with the incubation period for the illness experienced by those who ate the food, the strength of the association between the

foods prepared by the employee and the illness that followed consumption, the biologic plausibility of the food serving as a vehicle, and for the cessation of contact with the food worker with the food in question resulted in a reduction in disease, also, consistency of the findings with previous reports, and finally, the likelihood or unlikelihood that alternative explanations could account for the illnesses. Next slide, please.

Additional criteria or laboratory evidence of pathogen excretion at the time of food preparation, either by culture of the etiologic agent from worker specimens suggesting infection or serologic evidence of infection, also, a symptom history which was consistent with infection at the time of food preparation. Next slide, please.

Of the 138 articles identified, 72 were suitable for presentation. Several described more than one outbreak, so that 81 foodborne outbreaks were described. Excluded articles lacked sufficient detail or were review or background articles which did not present new information. Next slide, please.

Approximately 80 percent of the outbreaks occurred in the United States. Eighty-nine percent of outbreaks occurred in food service establishments, and 11 percent of

outbreaks were the result of foods prepared in domestic settings. Next slide, please.

Almost 15,000 people became ill in these 81 outbreaks. Four-hundred-and-forty required hospitalization. Two patients died. The outbreaks ranged in size from five to 3,175 people. Next slide, please.

In the 72 articles reviewed, 16 organisms were identified as the etiologic agents. Hepatitis A and Norwalk-like viruses were the most frequently reported and accounted for over 60 percent of all outbreaks in this review. Next slide, please.

Contributing factors in the 81 outbreaks. Seventy-five of the outbreaks involved food handlers who were infectious either prior to or at the time of the outbreak. The remaining six outbreak reports provided insufficient information regarding laboratory test results of implicated food workers who denied illness. In 34 of the 81 outbreaks, the authors specifically listed hand contact as a factor in transmission. In 14 of these outbreaks, it was reported that the workers were not wearing gloves. Four reports mentioned that gloves were worn, but were not worn during food preparation or were inadequate to cover infected hand lesions.

In an additional 38 outbreaks, the authors implied by description of poor hygiene practices that hand contact may have been a factor in pathogens transmission, either by inadequate hand washing or other factors. In the remaining nine outbreaks, the authors did not specifically mention how the food worker may have transmitted the organism to the food. However, all implicated food workers in these nine outbreaks were ill. Next slide, please.

These are two examples which represent fairly gross contamination. In the first, staff members experienced an outbreak of Shigella sonnei in gastroenteritis in the week prior to an outdoor festival. Preparation of cold ready-to-eat foods led to an outbreak involving 3,175 people. A few food preparers were still symptomatically ill with febrile diarrheal illness during food preparation for the festival. A non-cooked tofu salad had been thoroughly mixed by hand by staff and volunteers with limited access to proper hand washing facilities.

In the second, a bakery worker experienced vomiting and diarrhea while preparing buttercream frosting. We should be on the next slide. The employee prepared frosting by submerging his bare arm up to the elbow in the frosting as it was being mixed in order to scrape the sides of the vat. The subsequent outbreak of Norwalk-like virus

infection involving 129 people resulted from ingestion of frosted items that were contaminated by the suspected source case. Next slide, please.

These two examples represent relatively little contact with a prepared food. In the first, an outbreak of Hepatitis A that affected 30 people, the implicated food worker merely added lettuce and tomato to sandwiches and placed them on a plate after they had been grilled.

In another outbreak of Hepatitis A, an implicated bartender mixed drinks and added garnishes to beverages, but was not involved in food preparation. The bartender reported experiencing cough, nausea, and vomiting three weeks prior to the outbreak and was subsequently diagnosed with Hepatitis A. Next slide, please.

Specific food items were implicated as vehicles for transmission in 98 percent of the outbreaks. Sandwiches, salads, and other cold foods accounted for the majority of foods involved in the outbreaks. Next--can we go back one?

There were several limitations inherent in this review. First, the reports of foodborne disease outbreaks identified in the published literature represent only a small fraction of foodborne disease outbreaks and an even smaller fraction of all foodborne disease. The likelihood

of an outbreak being brought to the attention of health authorities depends on a variety of factors, particularly to consumer and physician awareness.

A second limitation of the review is that the studied differed in the extent to which the outbreaks were investigated or reported, and uniform data were not presented regarding the role of hand contact in all of the outbreaks. Next slide, please.

Because of the limitations described above, it is most likely that this review markedly under-represents the true number of foodborne disease outbreaks related to food workers. Additionally, one cannot establish from this review the true role of hand contact by food workers in the total burden of foodborne disease.

Despite these limitations, several themes emerge. First, numerous examples of foodborne disease outbreaks were identified in which hand contact of foods by food workers was believed to be the source of infection.

Second, both viral agents as well as bacterial pathogens were involved. Parasitic agents were less common.

Third, in addition to contamination of food by food workers, a number of other substandard food handling practices were often involved. Next slide, please.

We feel the following conclusions are justified. The review provides evidence that food workers, especially ill food workers, can be the source of infection and foodborne outbreaks and that hands can transmit pathogenic organisms to foods, so that removal of ill food workers from food preparation responsibilities is one possible intervention strategy to eliminate the source of foodborne infection. Thank you.

DR. POTTER: Okay. Thanks. The next presentation, by Dr. Hedberg, and while Craig is getting up to the podium, for the committee, I have received a point of clarification on Bob Buchanan's question to the first panel, and that is the bare-hand question to be addressed includes not only the fecal-oral but also, as Bob asked, other pathogens of human origin and cross-contamination issues from contaminated sources to ready-to-eat foods, although fecal-oral is perhaps the most commonly considered group of pathogens for hand transmission.

DR. HEDBERG: Good morning. Thank you for inviting me out here. It is my pleasure to come talk to you today about the epidemiology of foodborne disease outbreaks associated with bare-hand contact of ready-to-eat foods at retail, and I will be talking almost exclusively about our experiences in Minnesota, where we have actually had a

number of outbreaks with a variety of pathogens, from the Calici viruses, Salmonella, Shigella, Enterotoxigenic E. coli, Campylobacter, Giardia, and Cryptosporidium in which bare-hand contact of ready-to-eat foods was the likely source of transmission.

In addition to the issue of stool contaminating hands contaminating foods, I think hands play an important role in contaminating ready-to-eat foods by carrying pathogens from raw foods and contaminated surfaces. In your deliberations of potential mechanisms to deal with the problem of--okay.

[Pause.]

DR. HEDBERG: I had a great epi curve. I was going to say that as Dr. Barker represented, the problem of bare-hand contact of ready-to-eat foods was dramatically brought to our attention in 1982, and this was an epi curve showing the outbreak associated with the bakery products. In one evening's production of 76 liters of frosting on 10,000 bakery products, a frosting maker who produced the frosting had five episodes of diarrhea, two episodes of vomiting during the six-hour shift, with bare arm up to the elbow in the frosting during the manufacturing process and 3,000 estimated illnesses.

Now, this is sort of extreme bare-hand contact with ready-to-eat foods, but it really opened our eyes to the importance of these viral infections as a foodborne illness. In Minnesota, we have continued to see Norwalk-like viruses as a major source of foodborne disease, accounting for 41 percent of our outbreaks during the 1980s and 1990s. In a high proportion of these cases, we do find ill food handlers who handled the implicated food items.

In addition, we found a number of instances in which, although the food handler denied any illness, there was illness identified in household members, suggesting either asymptomatic infection or the food handler actually carrying the virus in on hands or clothes. In the high proportion, we see transmission in restaurants which leads to the propagation of outbreaks. I guess it is not going to like any of my epi curves.

We also have seen an outbreak of Salmonella enteritidis infection at a fast-food restaurant in Minnesota. I can print out my slides for you to look at, I guess, at another time since this doesn't seem to like what I've done here.

MR. POTTER: Craig, can you do your presentation without slides?

DR. HEDBERG: It loses a lot of its value, but I can certainly do that, and then we can provide a printout for the group.

MR. POTTER: The slides will be available for the committee's use tomorrow.

DR. HEDBERG: Sure. The outbreak of Salmonella enteritidis at a fast-food restaurant occurred as a result of a counter worker who handled ice and curly-fried potatoes had onset of gastrointestinal illness, and during several days, worked while ill. There was approximately about a three percent attack rate during the early stages of the outbreak while this employee worked. Subsequently, she developed diarrhea and stayed home from work and transmission continued to occur as a result of other food workers being infected with Salmonella. During those other shifts, the food items associated with illness were all quarter-pound hamburger, which required extensive hand preparation, putting toppings on. That outbreak was published in the literature, as well.

We had a subsequent outbreak involving Salmonella typhimurium at a table service restaurant, in which it was presented to us initially as a result of molecular subtype work, looking at Salmonella typhimurium infections, and we identified that patrons and employees of this restaurant

developed diarrheal illnesses over a period of two weeks. The illnesses were all associated with eating salad items.

When we looked a little more closely, the illnesses were associated with eating salad items that were handled by one particular person. On days when that person was not working handling salads, there were no illnesses attributed to transmission by salads. That salad maker denied any history of diarrheal illness or any other gastrointestinal symptoms and we did isolate the outbreak strain of Salmonella Typhimurium from her stool.

One of the things that we've seen as we have looked at the question of Salmonella in outbreaks in restaurants is that we have now made interventions in a number of outbreak settings where we've gone in and cultured all food service workers and service staff in the restaurants and found up to a quarter of the workforce infected with Salmonella during some of these outbreaks.

Although we typically look for symptoms of fever and diarrhea in patrons that leads to their detection, there is a much milder illness picture that we see when we can comprehensively survey the entire workforce and look for Salmonella. In fact, in a number of instances, we've had between one-third and one-half of the employees who were

infected with Salmonella reporting asymptomatic illnesses, not reporting any symptoms of diarrhea.

To complicate the problem, as we have followed these employees out over time from the point at which we've made our intervention, we have seen a small percentage of employees continue to shed Salmonella in their stool for up to two months after the point of the intervention, and the median carriage after intervention was up to two weeks. So these employees in outbreak settings likely do provide a reservoir mechanism for continuing to provide a source of exposure to patrons.

That is a real concern, because we have had a number of outbreaks in restaurants where we've had extended transmission of a highly-conserved organism based on its pulsed-field gel electrophoresis pattern for up to three months, and a lot of that is probably mediated by food handlers interacting with the environments in the commercial food service kitchens.

We had a very large outbreak of Shigella sonnei infection involving the Minnesota Vikings and Northwest Airlines which was published in the literature. More recently, last year, there was an outbreak of Shigella associated with parsley that was imported from Mexico. In two restaurants we had in Minnesota, food handlers became

infected and appeared to play a role in propagating the illness in those outbreaks.

At the same time as our Shigella outbreaks occurred, we had two outbreaks of Enterotoxigenic E. coli occurring, also likely due to parsley coming in from Mexico, and in both of those outbreaks, following an initial wave of cases which was likely due to contamination of the parsley, there was a two- or three-day window where there appeared to be little transmission but during which food handlers became ill, and then following the illness in food handlers, we saw a second wave of cases in these restaurants.

We also recently had an outbreak in Washington County, Minnesota, of Campylobacter jejuni at a restaurant, 42 confirmed and 110 probable cases. The illness was associated with consumption of lettuce, and most of the exposures occurred over a two-day time period. There were no food workers who had been ill before the outbreak, but on June 2, a large volume of lettuce had been prepared by a chicken prep cook. The cook was basically pulled off the line after working with chicken and asked to make up this lettuce. The lettuce washing procedure involved putting the lettuce in a food prep sink filled with water. The food worker then stirred the lettuce with immersed arms and hands in the water. The mixture was then drained, bagged, and

stored in the cooler and used over the next two days. That led to this large outbreak of illness.

We also have documented illnesses associated with Giardia and Cryptosporidiosis. In both cases, events which occurred as a result of somebody diapering a child and then going and preparing a salad item, canned salmon in one case, a chicken salad in another, in which there was extensive hand contact. In both of these instances, the person who prepared the food claimed that they washed their hands well. There was no evidence to suggest that there was a particular problem with their hygiene. But then they subsequently washed their hands in the salad and these outbreaks occurred.

Now, these were not in commercial establishments, but I think the basic principles of transmission with these parasitic agents probably are occurring in commercial establishments, as well, and the state of our surveillance for most of these agents is sufficiently low that outbreaks like this probably go on around us frequently without our knowing it.

In conclusion, the contamination of ready-to-eat foods by bare-hand contact, I believe, is a generalized problem. It is not restricted to a particular pathogen or group of pathogens. I think the demands of producing ready-

to-eat foods and the extensive manipulation of these foods really creates a tremendous challenge to doing so in a way that doesn't permit contamination by hands.

I apologize for my slides, but I will make them available to you in printed format. Thank you.

MR. POTTER: Thanks, Craig. I appreciate your willingness to forge ahead there.

Our next speaker is Dale Morse. If we can get that miserable computer out of there, I think Dale has slides.

DR. MORSE: Good morning. It's a pleasure to be here. I guess it's said you can't teach old dogs new tricks. One of the advantages of being an older speaker is you get to use old technology. Hopefully, the slides will work. Actually, I made them on Powerpoint and then made slides from the Powerpoint.

It is a pleasure to be here and away from simultaneous outbreaks of St. Louis encephalitis and the E. coli 0157 in New York. Fortunately, the E. coli 0157-87 seems to be winding down. We had over 1,000 cases, 62 hospitalizations, two deaths, but it looks like it was waterborne. But then you get into the question of definitions. It was a waterborne outbreak, but the water contaminated lemonade, ice tea, snow cones, so I guess

that's still water, but it makes you wonder what the definition of food is.

I'm going to talk a little bit about New York's experience in terms of the role of food workers in foodborne outbreaks, looking at past historical data from 1980 through 1995. This is preliminary information in that we have a graduate student at the School of Public Health who is working on this data for her thesis and she was told that she basically has through December to finish this, so she was a little bit panicked when we asked to put some of the information together for this report. So this is preliminary. We have cleaned the data and gone through it, but there's still a lot more we need to do. The number of people that have worked on this, I've listed some of the people here.

The objectives of our investigation were three. One, to assess the contribution of ill food workers to foodborne outbreaks in New York State over a 16-year period. We're expanding that to include 1996 and perhaps other years if we can. Second, to describe the characteristics of outbreaks where food workers were involved. This is mainly descriptive information. And third, to compare some of the differences between outbreaks where food workers were and were not involved.

As background information, I should tell you a little bit about New York State's foodborne disease surveillance system. New York State has 18 million people. There are 57 county health departments, five boroughs in New York City. The foodborne disease outbreaks are reportable to the State Health Department through the local health departments. The local health departments are where investigations take place. When a foodborne outbreak is reported, they initially call it in to the central office and an investigation is begun. At the conclusion of an outbreak report, a summary report is filed with the State Health Department and then reported on to the Centers for Disease Control.

There are at least three units in the Health Department that work on foodborne outbreak investigations. The Center for Environmental Health controls the surveillance system of all reports. The Epidemiology Unit investigates outbreaks involving reportable communicable diseases, such as Salmonella, Shigella, E. coli 0157-87, and Listeriosis and others, and the laboratory, and there is fairly good collaboration between all those groups.

If you look at the trend for outbreaks over time that have been classified as foodborne outbreaks where food has clearly been associated with illness. This shows the

number of outbreak reports. A couple of points to make is that this is a final number. Initially, there are four to five times as many reports that come in, so this represents 20 to 25 percent of the initial reports where there is sufficient information to show an association with a food product.

Early on, this system was set up by Jack Esache [ph.] in our State, and in the first couple of years, Jack, I, and several other people had a number of workshops around the State to train sanitarians and nurses in how to investigate and follow up on foodborne-related outbreaks. From 1982 through 1985, we had a series of outbreaks associated with shellfish, and from 1986 through 1992, a number of Salmonella enteritidis outbreaks occurred, over 100 of them, with over 86 associated with eggs. In the last couple of years, you can see there's been a slight decrease in the number of outbreaks reported and we're looking at that more closely to see what could be contributing to that.

From this database, we're able to look at a number of different variables. From this, we're able to do things like show the contribution of different--so, for example, we're able to show that 34 percent were bacterial, 25 percent viral, chemical eight percent, and again, we have a large proportion that are unknown. Looking at those

outbreaks, a lot of those appear to be viral in terms of their characteristics.

Other things that we do with these outbreaks is classify contributing factors that are associated with the outbreaks, so there are a number of factors that are associated--contaminated ingredients, things like inadequate heating or cooling, but of note, an infected food worker has been a contributing factor in about 22.5 percent. In terms of definition, this requires that the food worker has to have been ill prior or during the time that the meals were served and is clearly associated with in terms of some kind of contact with the food item and likely to be the source of the outbreak. So for those outbreaks where we've been able to look at contributing factors, food workers have a significant effect.

I'll talk a little bit more about the role of infected food workers, but we should add a quote. This is showing that history has talked about food workers a long time. In this way, a dirty cook gives diarrhea quicker than rhubarb. Actually, I didn't know that rhubarb gave diarrhea, but historically, there have been lots of reports, and New York was famous for Typhoid Mary in the early 1900s and her role as a food worker. That was a fast version.

Looking at our food outbreaks, we've classified those. We had, as I mentioned, 1,800 outbreaks involving over 40,000 cases, and looking at, individually reviewing these outbreaks to see where you could determine whether a food worker had a role or not, of those outbreaks, 916, there was sufficient information to classify whether a food worker was involved. Of those 206 outbreaks, a food worker was implicated, and 704 outbreaks, a food worker was clearly not related, and six we're still reviewing that are suspicious for a food worker. So we're going to look at the 206 outbreaks and compare versus the 704 outbreaks.

Looking at the outbreaks again, this is, again, the same basic figure in terms of outbreaks over time and this in red shows the proportion where a food worker was implicated. Basically, you can't see the small numbers, but this shows the percentage of outbreaks that were related to food workers over time. The first five years, we feel this information may have been incomplete because of the training and gearing up. Also, there were a large number of clam outbreaks which were not associated with food workers. But the percentage has fluctuated, ranging from eight up to 16 percent, but it has been fairly constant, around ten percent overall, but over 20 percent of those where we're able to

look at food workers' role, and 1996 looks similar, 106 outbreaks with 12 involving food workers.

New York State has a regulation in August 1992 to require that food workers do not have direct hand contact with food, though it's a little early to say that this was the result of that because all outbreaks came down, as well. So you could argue that some of these may have been related to food workers' involvement.

There are some differences between outbreaks where a food worker is involved and those where a food worker is not. One of those big differences is the proportion of outbreaks that are viral in nature. Approximately 53 percent where a food worker was involved, versus about 30 percent bacterial. This is about the reverse of those outbreaks, 704 where food workers are not involved were bacterial, contributes to 51 percent, and viral, only about less than 30 percent.

This is hard to read. This shows the agents that were involved in food worker-associated outbreaks, and again, viral-like outbreaks were the leading cause, in this case, 72 of the 206 outbreaks. Salmonella was the second-leading, with 42. And then some other viral agents, such as Hepatitis A, Norwalk, and Rotavirus had large contributions.

Almost all these agents are fecal-oral in terms of transmission, except for Staph aureus and beta strep.

We were also looking at other potential contributing factors. The contributing factors we list. We don't limit ourselves to one; there's multiple. Those foodborne disease outbreaks where food workers are implicated, also only about a third of those report actually direct hand contact where it's documented. There are some other contributing factors which we need to analyze to see how much role they could play. Some of those are not unexpected in terms of inadequate heating or cooling, because if the food worker contaminates the food and if it were a food item that's cooked adequately, you'd basically kill the organisms. So there's maybe a combination of factors involved in these type of outbreaks.

This does differ considerably from the outbreaks where food workers are not implicated and a proportion of contaminated ingredients being the leading source of a problem in terms of those outbreaks. A number of other factors are involved.

One other thing we've noted is a difference in size of outbreaks where a food worker is involved and where a food worker is not implicated. The size of the outbreaks is larger, with a mean of 50 cases versus 22, a median of 23

versus 7, and larger outbreaks ranging up to 1,300. So the outbreaks tend to be larger where a food worker is involved.

One other factor, and this, we're still, as I mentioned, in the process of analyzing information--

[Pause.]

DR. MORSE: As I mentioned, we're still beginning to look at this information--can everybody hear me? No?

We're still looking at the information. There are a number of differences between outbreaks where a food worker is involved and where one isn't in terms of types of food involved. I think I won't go through this busy slide, but one of the main differences that we've noticed is a food worker contaminates multiple foods, but salads and sandwiches, not unexpectedly, play a larger role than where no food worker is involved, where salads with raw ingredients, sandwiches play a much smaller role, and this would be expected with direct hand contact. Where no food worker is involved, you tend to have foods that are eaten raw or lightly cooked. So there are some differences we are just starting to look at in terms of these outbreaks.

We've also had some experience directly with Hepatitis A outbreaks and the role of a food worker. Onondaga County is where Syracuse is located, and in 1987, they noted a marked increase in Hepatitis A cases. They

normally only had two to five cases per quarter. They had over 30 cases in a very short period of time. There was an outbreak of Hepatitis A among food workers, somewhat associated with drug use and sharing of marijuana and drugs in this population. So there are a number of food workers that developed Hepatitis A because of those outbreaks and there were two actually foodborne outbreaks with transmission to people eating foods.

During this time, the county health commissioner in 1997 ordered a glove order that all food workers had to wear gloves. This was later revised later that year to say no hand contact, where they could use tongs and other things in the preparation. But after these two foodborne outbreaks with Hepatitis A in food workers, 30 clinics were offered where immunoglobulin was given preventively and they administered over 25,000 immunoglobulin shots. This was a result of 45 food workers that had Hepatitis A.

Finally, when the industry was using gloves and following up, they reached an agreement where if the food worker was documented as having had no direct hand contact, that they wouldn't go public and they wouldn't have a clinic to give immunoglobulin. There were 15 of these instances where there was compliance, no public notification, and no secondary cases were found.

What happened since then, between 1992 and yesterday, there have been five other food workers that have been found to have Hepatitis A. One of those had documented some contact with hands with food and a clinic with 488 doses of immunoglobulin was offered. The other four, there was no clinic.

MR. POTTER: Wrap it up, if you could.

DR. MORSE: Okay. I just want to end on a point about education. I know somebody else mentioned this earlier. I think education is sort of missing here. I know we are told that food workers are low paid and can't afford to do things. Having had two daughters that were lifeguards, also a low-paying job, I noted that they also get minimum wage but have strict requirements, at least in New York State. You have to be 15 years of age. You have to take a course for 40 hours. You have to repeat it every three years. And you have to have CPR testing. You have to pay the expenses yourself, $140 plus a $35 pool fee. In contrast, food workers' training in New York State, there is no Statewide legal requirements for training.

If you go on beyond that to teach other people, to be an instructor, you have a minimum requirement first of having to have lifeguard certification, which is the previous 40 hours and $130, you have to have a 60-hour

course, you have to pay $175, plus a $35 pool fee, and if you're a food worker-instructor-manager Statewide, there are zero requirements. It is up to the localities, though, and 12 of them do require some type of training for the instructor.

So there is a discrepancy between requirements between people that handle food and people that in swimming. There are 5,000 deaths a year due to foodborne disease. There are about 400 deaths a year due to drowning.

In summary, some of the points we've found so far, food workers have contributed significantly to foodborne outbreaks over time, 23 percent of the outbreaks where we have been able to make an assessment. Food workers associated with total foodborne outbreaks have decreased over time, but it's too early to say whether there's association with our no-hand contact. And food workers associated with outbreaks have most commonly involved virus-like particles, 40 percent, Salmonella, 20 percent, Hepatitis A, eight percent, and food worker-associated outbreaks were more likely to be viral and larger in size. Thank you.

MR. POTTER: Thank you. The last speaker in this section will be Dr. Steve Monroe. Out of respect for the

difficulties we have been having with technology, he's going to have his graphics on clay tablets.

[Laughter.]

DR. MONROE: I have my backups as overheads, but if it's taking more than 30 seconds, we'll switch.

I want to thank the committee for inviting me here. I'm Steve Monroe from the CDC in Atlanta and the Division of Viral Diseases, so my presentation today is going to focus on the viral agents. I'll start with this recent data, and it's available on the web. The website is here. The hard copy form will be published next month.

It's a little embarrassing for me to follow up Craig Hedberg and Dale Morse because they have real data from their States where they have good surveillance systems. A lot of the data that I'm going to show you is sort of hypothetical data and there's a lot of assumptions that go into this table.

Again, the total here, the top number in each row is the total illness, gastrointestinal illness estimates, and the bottom number in each row is the number that's predicted to be foodborne. So, again, 38 million total cases of illness, of which 13 million are presumed to be foodborne, with the viral being the largest component of

illness and bacterial being the largest component of the deaths and parasitic being a smaller component of both.

What I'm going to start with, and try to do two things here. One is to give you a little bit of sense of the real data that we have from our group at CDC in looking at outbreaks of gastroenteritis and talk a little bit about our system and how we get data, which is completely passive, and then give a few examples at the end of specific outbreaks which, I think, highlight individual points that are important for your discussion on how to proceed.

The review I am going to talk about first is outbreaks of non-bacterial acute gastroenteritis that are reported to our group, and so, in general, outbreaks that are bacterial in nature, the clinical diagnosis is made at the State health department or a clinical lab and so those aren't reported to us. But if they're non-bacterial, then the local or State health departments may give us a call.

We reviewed two years of data, from April of 1997 through March of 1999. During this time period, there were a total of 154 outbreaks of non-bacterial acute AGE reported to our group at CDC, and of these, I'm going to present an analysis of 132 where there was enough data available, descriptive, to make some picture of what's going on, and then adequate specimens for us to test in the laboratory.

The focus here is going to be on NLV, or Norwalk-like viruses, and I'll give a little introduction of that in a minute, and we're using an RT-PCR-type approach for diagnosis.

Norwalk-like viruses, and I apologize for those of you who are not in the field, the terminology is a bit confusing. It's confusing for those of us in the field. They're currently now officially classified in the family Caliciviridae, so they're also referred to as human Calici viruses, and there's a newly described genus within that family called Norwalk-like viruses, in quotes to indicate that it's an interim name until they can come up with an official Latinized name for these viruses. But for the time being, I will call them NLV, or Norwalk-like viruses.

They're RNA viruses. The important point for this discussion is there's no animal model or cell culture system, and so historically, diagnosis was made based on using reagents from human volunteer challenges, and it was only with the advent of molecular biology, the cloning and sequencing, developing of PCR detection techniques, that we've been able to get a real handle for how important these viruses are. So the historic importance of these viruses is grossly under-represented.

Let's get to the bloody details here. This is basically what goes on in our laboratory, what I call stool cup to sequence. So what we get from the State and local health departments are stool specimens. We do have an electron microscopy facility where they look directly for the virus by EM, but our normal protocol is to do an RT-PCR. Originally, we used the probing method to distinguish different probe types. Now, we simply cut out the band from the gel and go to automated sequencing and do a sequence profile. So this is our equivalent of the pulse field for strain identification of Norwalk-like viruses.

Now, looking at these 132 outbreaks over a two-year period--I should point out, this is a completely passive system, so there's no requirement for States to report to us and they only do so if they're so inclined. Some States are much more likely than others to send samples to us and contact us and so it's a gross underestimate and it's a skewed picture, but it's the best that we have available.

So of these 132, 27 percent of them occurred in restaurants and were clearly foodborne. Our largest fraction actually was in nursing homes, where you have a lot of people in close contact and there's a lot of chance for person-to-person transmission. Some of these may well have

started as foodborne outbreaks that were then spread by the person-to-person transmission. Similarly, we have outbreaks in schools. We know that some of these start as foodborne outbreaks and are spread. Then what I've called here vacation settings, this would include cruise ships, summer camps, things like that. Again, a number of these begin as foodborne outbreaks and are then spread.

So in total, we estimate that about 40 percent of our outbreaks are foodborne, when you put them all together, and so it's the same number that Craig Hedberg has, but we're looking at it a different way. In Craig's data, 40 percent of the foodborne outbreaks are viral. In our data, 40 percent of the viral outbreaks are foodborne.

Now I'm going to go through a couple of the examples of these and highlight some of the features that I think are relevant for the bare-hand issue. This is a study that's to be published in the Journal of Infectious Diseases.

There's a university dining hall, and this is March of 1998, acute gastroenteritis associated with students who ate lunch or dinner, particularly from a deli bar at the dining hall. One of the other things I want to point out during this talk is that the increased awareness that viral infections, although previously thought to not be

serious, can result in some serious illness. So during this outbreak, 23 of the students were hospitalized. We received 18 stool samples. Nine of these were positive for a Norwalk-like virus by RT-PCR.

The food handler who was responsible for working at the deli bar declined to be interviewed and was suspended from her job for two weeks. After two weeks, she finally agreed to be interviewed. At that point, it was determined to be too late to have a specimen collected. But what she did report is that although she denied being ill during the time that she was working, she did say that she had a child who was symptomatic throughout that entire two-week period. We obtained a specimen from that child two weeks after the outbreak. That specimen was PCR positive and the sequence from that specimen was identical to the sequence from the students.

In collaboration with a group at Baylor University, they obtained samples from the deli bar, the food items, and were able to test those and found a ham sample was RT-PCR positive. The sequence from that virus matched that found in the ill child and in the students, showing the link between the food item itself and the ill students.

So I think this raises the specter here, as someone had previously pointed out, that we have to be concerned about illness not only in the food handler but in household contacts of the food handlers, as well. This makes it a little bit difficult to exclude people from work.

The second outbreak I want to talk about was a catered luncheon in March of 1997, acute gastroenteritis associated with sandwiches, a relative risk of 14, highly significant, of those employees. So the situation here was a manufacturer wanted to be nice to his employees so he decided to have a catered lunch. They contacted a local deli to prepare sandwiches. They had a buffet set out with the sandwiches and the attack rate was about 36 percent in those employees who filled out the survey.

Again, we received 20 samples, seven of which were positive for Norwalk-like viruses. So in this establishment where the sandwiches were prepared, one food handler reported illness four days prior to preparing the sandwiches but claimed to be symptom-free at the time the sandwiches were made. Another food handler, who was actually a sister of this food handler, denied being ill at any time in the previous two weeks or two weeks afterwards. Both of these food handlers were positive for virus, in one case only by electron microscopy, in the other case, both by electron

microscopy and RT-PCR assay. Gloves were not routinely used at all in this establishment. This work has been published.

So, again, here we have the issue of someone who is ill and then resolved illness and then also perhaps an asymptomatic food handler who was shedding virus, even though not reporting symptoms.

Then, finally, a third example here was an Army training center in August of 1998, acute gastroenteritis associated with breakfast at mess hall A, and interestingly, the food items that came out in analysis were crumb cakes, cinnamon rolls, and pie--for breakfast. Again, looking at the severity of the illness, 99 soldiers were hospitalized, presumably healthy young adults. We received 24 specimens. Seventeen of these were positive for Norwalk-like virus. Similar to the outbreak that Craig Hedberg described in Minnesota, the confection baker admitted being ill while on the job while preparing the baked items that were served at breakfast, and this has been described in the MMWR and will be written up as a separate publication.

So, again, here we have an example of foods that are not traditionally thought of as being at high risk, like salad items and things like that, baked confection items, but if you have any item that is not thoroughly cooked after

preparation and involves a lot of bare-hand contact, then the potential for disease transmission exists.

Just one point to finish up on the Norwalk-like viruses. As you saw in each one of those cases, we never had 100 percent detection of virus in stool specimens from the patients who were clinically ill. So our viral diagnostics are not 100 percent sensitive and it makes it a little bit difficult for us to get information on the background rate in the community because we know that even our current tests are underestimating the true fraction.

Then I want to talk a little bit about Hepatitis A, and this, again, involving a bare-handed food handler. This is an outbreak that has been reported--published--this year. Here is just the time line of what happened. On the 18th of October, the food handler developed diarrhea, the next day, visited the ER, was clinically diagnosed as Hepatitis A, but there was no reporting. So six days later, the food handler visited a physician, was serologically diagnosed as Hepatitis A.

This physician notified the health department and an investigation started. The health department investigated the caterer, reported no violations in food preparation. The food handler was judged to have good

hygiene, and so they recommended against any public notification or IG.

Then in the first three weeks of November, there were 29 cases of Hepatitis A in patrons of this catered event reported to the public health department. Here's a little epi curve to show--the red bar here represents when the events occurred that were later associated with illness. The 18th was when the food handler was first diagnosed. What's interesting is that there were events that occurred two days after the diagnosis when the food handler stopped working, and again, it was food that the person had come in contact with but was stored and was served at later events. This is the epi curve of the total number of cases. The total number of cases identified by the follow-up survey was actually 91.

One of the things that came out of the analysis here of what the contributing causes were to this event by looking at events that were associated with illness, compared to the catered events that were not associated with illness, two things that came out were, one was having a kitchen onsite. Since these were catered events, some of them were outdoor events, things like that. So not having a kitchen onsite did have an increased relative risk, though not significant. In particular, not having a sink onsite

had a relative risk that was significantly associated with the Hepatitis A. So the presumption would be here that without a sink, there was no way for the food handlers to wash their hands.

So that is really the end of the data, and I think that the important points I want to make are because we now know that there typically can be asymptomatic shedding of virus and that people who have household contacts that perhaps have virus infection can transmit to food items, the whole issue of trying to exclude from the workplace workers who are ill will not eliminate having food contamination. I mean, it makes sense to eliminate somebody who is vomiting and diarrhea shouldn't be making the frosting, but just because you're not actively symptomatic doesn't mean you don't have the potential to transmit. Thank you.

DR. POTTER: Thanks, Steve.

We have a couple of minutes here for questions from the committee for Steve, Dale, Craig, and Eileen. Yes, Alison?

DR. O'BRIEN: Hi, Alison O'Brien. I have a question for Craig.

DR. POTTER: Craig. Alison, get a little closer to your mike, please.

DR. O'BRIEN: My question has to do with sick leave for health care workers--not health care, I'm sorry, food handlers. My concern is that if we are encouraging them not to handle food when they may have had mild symptoms or they have a child at home that's sick and they're sort of waffling because money is an issue, in your investigations, did many of the food handlers actually have sick leave that they could take so they'd still get paid during the interval of being off the job?

DR. HEDBERG: In our investigations, in probably most restaurant settings, food handlers have not had sick leave so they could take time off the job. The other problem is that in a number of outbreaks we've been involved in, there were practices such as if an employee wanted to take time off of work, they were responsible for finding their own replacement. With the labor shortages as they are, I think there is increasing pressure being put on management and workers to allow workers to work as often as they can.

DR. O'BRIEN: Thank you.

DR. POTTER: Other questions on the issues of science here? Katie?

DR. SWANSON: I have a question for Craig. In the retrospective studies that you've done on following up on

the outbreaks, were the employees that were working in those restaurants wearing gloves or not?

DR. HEDBERG: We in Minnesota have never made an effort to get food service workers to wear gloves, and in these particular settings, gloves were not worn.

DR. SWANSON: Thank you.

DR. POTTER: John Kobayashi?

DR. KOBAYASHI: I believe this question is for Craig, but also for Dale. Is it possible to separate out on your data the events where there was a food handler who was ill while handling food versus where there was no bare-hands contact and whether or not that happened at the same time?

DR. HEDBERG: So you want to--I don't think, in our data, we could do that. I don't know that there would be, frankly, enough situations where we could show a food worker being ill in a setting in which there was no opportunity for bare-hand contact to play a role within the Minnesota data.

DR. POTTER: Dale, did you want to amplify that?

DR. MORSE: I think it's a similar experience. We had 33 percent of the outbreaks where we had documentation there was direct food contact, and we will be looking at that and comparing it against the other two-thirds, but we would be skeptical about the information. Again, as has

been mentioned before, food workers work ill, and if you interview them, they're not quite often going to admit to that because they'll be laid off or lose their job or have to go home and not get paid. So reporting is inadequate to rely upon, and some surveys have suggested that 80 percent of the food workers may, in some of our surveys, have worked in the past while ill.

DR. POTTER: Stephanie, and then--

DR. DOORES: Stephanie Doores, for any of the speakers. Have you noticed in any of your data that there is any difference between workers involved in incidents from national chains or fast food restaurants versus other types of restaurants?

DR. HEDBERG: Do you want to start with that, Dale?

DR. MORSE: You're going to avoid that. Some of the national restaurants have gone to voluntary training programs. I mentioned in New York State we now have a Statewide mandate for training and education. Some localities can have the ability to do that, so we have noted that some of the chains are very conscious of publicity and have instituted programs on their own. Of course, now in New York State, there's no food contact regulations, so all food establishments are held to the same inspection and

requirements, so it's a little bit hard for us to tell. Now it's your turn.

DR. HEDBERG: I'd say that we certainly have had outbreaks as we've described in settings involving national chains and settings involving the mom-and-pop restaurant. What I can't do for you right now is put any perspective on that in terms of the number of--the denominator of restaurants that are available to compare rates of occurrence, and that's, I think, one of our needs, to really begin to explore sort of the predictive value of some of the hazards that we're encountering.

DR. MORSE: I think this points out the need for some prospective studies to look at this question. I mean, a lot of what we've been doing is going back and looking retrospectively. I don't know Minnesota. New York would certainly like to do this prospectively, looking at more in-depth risk factors.

DR. MONROE: And at CDC, I mean, we have, again, no denominator data, but we have examples both from national chains and from individual restaurants. So the situation does occur, but what the relative proportion is, we don't have any way to assess.

DR. POTTER: The last question.

DR. ANDERS: Yes. Dr. Hedberg, especially, you mentioned that in the Salmonella, that some of these patients still were shedding after two or three months, but one of the questions come up then, was were they treated, because treatment tends to cause carrier in Salmonella, so I guess that's a question in my mind. The second thing was, after treatment, were they allowed then to go back to work, or how did that occur?

DR. HEDBERG: We have, in a number of outbreaks we've made these mass interventions, we've had employees go in and seek physician care, and a number of them have been treated. What we do with that is basically to continue to--well, we talk to the physician and recommend that they not be treated, but if they do remain treated, we'll continue to exclude them until some point after the treatment to get a follow-up culture to establish whether or not they're continuing to shed. But these long intervals are really not primarily due to treatment.

DR. POTTER: Okay. The last presentation this morning before break will be on quantitative risk assessment, Dr. Don Schaffner from Rutgers.

QUANTITATIVE RISK ASSESSMENT

DR. SCHAFFNER: Thank you for the opportunity to come here today and talk about some of the work that we've

been doing in our lab, looking at using the quantitative risk assessment approach to assess the effectiveness of various hand washing parameters.

First, a little bit of a background on what quantitative risk assessment is for those of you who may not be familiar with it. It is a way of representing information, published information in the scientific literature, mathematically. You can also represent expert opinion where you don't have sufficient data from the literature.

Another way of looking at it is as a computer simulation that will describe the risk of a particular event occurring. In this case, what we're describing is the probability of having a certain number of microorganisms left on the hands at the end of the hand washing process.

There are several key advantages to using a quantitative risk assessment approach like the one that we're using here. First of all, the variability and uncertainty of the data are naturally included in the end result. If you've looked at any of the studies on hand washing, what you find is that there's a high degree of variability, methodological variability, variability from individual to individual, and by using a quantitative risk assessment approach, that variability gets incorporated into

the results that you get at the end. So not only do you have a mean response, but you have some variability associated with that mean response. You have some indication of the uncertainty of the answer that you arrive at.

Another key advantage of the QRA approach is that the data that are out there that go into the risk assessment are organized into a form that can be easily analyzed and interpreted and critiqued and discussed, and I think you'll see that in some of the screen snapshots that I'm going to show you from our risk assessment.

Finally, or thirdly, quantitative risk assessment can identify avenues for future research. The risk assessment that I'm presenting here today is a preliminary one and there's not a lot of components to it because there weren't a lot of data in the literature that were available to us that we could incorporate here, and one of the things that I hope will happen as a result of me talking here this morning is that people who have unpublished data or who are more familiar with the literature base than we are that can identify perhaps some studies that we've missed that could be incorporated here.

Then finally, another key advantage, especially with the particular piece of software that we're using, is

that that risk assessment is not a static entity. It can be expanded as more data become available. I'll show you, again, a simple example of how we did that with our risk assessment at the end of my presentation here.

There are some limitations to this approach. First of all, the quantitative risk assessment will simulate data that are available. Data which aren't readily available, unpublished information, for example, can't be easily incorporated into the simulation.

And also, it's important to remember that what I'm presenting here today and quantitative risk assessments in general are really just a mathematical representation of what we think is occurring in the real world. It does not necessarily accurately represent what is happening in the real world.

For example, in our hand washing risk assessment, we're assuming that the steps in the hand washing process are cumulative. In our simulation, one particular step which removes a particular theoretical microorganism, we could be removing that same microorganism twice, counting it twice in the risk assessment. So that's why validation of any risk assessment is very important.

There are a number of limitations specifically to the risk assessment that I'm going to be presenting here

this morning. First of all, all of the data that we used that came from the literature were from experiments that used surrogate microorganisms, not pathogens.

Secondly, our simulation doesn't differentiate between transient organisms and resident bacteria that are present naturally on the skin.

A third limitation, which I think is especially important to note, given the other remarks that you've heard this morning about the importance of viruses, is that viruses are not included in our simulation, not because we didn't want to include them, but just because there weren't adequate data available in the literature to be able to model that process on the computer.

This is a brief summary of what we did to conduct our risk assessment. We did a literature search using online and library resources. We extracted data from the literature. We organized that information into spreadsheets and other computer programs. Information that was presented graphically were ungraphed. That is, we took data from figures and converted it into numerical information.

And then in certain situations where we had data from different studies studying the same factor, we combined them to create statistical distributions, and I have an example of that on the next slide. These are some data from

a variety of papers on antimicrobial soap effectiveness. What you can see is here is the frequency. This is the number of times that a particular antimicrobial soap appeared as a datapoint, or as datapoints in a scientific study. This is the log change, that is, the log reduction in the number of microorganisms.

What we decided in our risk assessment was that the antimicrobial soaps, Triclosan, PCMS, Iodophor, and some other miscellaneous antimicrobial soaps, we judged them to all be from the same statistical distribution. So you can see, this is not a normal distribution. It's actually slightly left-skewed with a longer tail here. Then we arrived at a mathematical distribution which described the variability in that data. We see a triangular distribution which is superimposed on that literature data. So now we have the same data, but now they're all colored the same color and we superimpose a distribution over that.

There's a whole lot of different statistical distributions that you can choose from. The triangular one is a very, very simple one, but obviously, you can describe these data with more complex distributions, as well. But I think this just makes the point of one of the ways you would superimpose a statistical distribution over literature data.

Then we created our mathematical model. The particular piece of software that we're now using is a program called Analytica, which is available from this company in California called Lumina. One of the key advantages of using Analytica is that many of you who use the Internet are probably familiar with Adobe Reader documents, where you can download the reader for free and look at these documents. The software that actually generates the documents, you have to pay money for.

Well, Analytica works the same way, so someone that creates a risk assessment using Analytica can share that. People can download the reader for free and test drive the risk assessment and look at the assumptions and play with the parameters of the model. So that's the software that we've used.

This is a screen snapshot from the program. There are several different things going on here. You see we have different node types. We have decision nodes here, where you would make a choice as to the type of soap, the type of drying method you would use, the type of sanitizer, and whether rings are being worn or not. We also have chance nodes. These are symbolized by the ovals here. This is where you have some statistical distribution, some variability associated with the different soap types or

drying methods or sanitizers, et cetera. Variable nodes are these here. Also, one of the other chance nodes is the initial number of bacteria present on the hands.

So based on the initial number and the variability of whichever soap happens to be used, you have some estimate of the number of bacteria left on hands after soaping, after drying, after sanitizing, including the effect of rings, and then some final log change, which is the difference between this last number and the initial count.

I'm going to show you a revised version of this at the end of my talk, just looking at these first few nodes here where we expand it based on some data from cross-contamination we collected in our laboratory.

One key advantage, also, in using this Analytica software is that this is not a picture that we created with a graphics program. This is actually from the software itself. So you can see our thought processes and how we decide how these different parameters interact. So this is actually an accurate representation, a graphical representation of the mathematical components of our risk assessment.

Well, this is supposed to be a slide showing the effects of antimicrobial soaps. Different antimicrobial soaps have different effectiveness. I apologize for this.

I assumed that I would avoid this problem by being able to run this off of my own computer, where the software is installed, but I see that I haven't avoided the problem. I'd be happy to provide a hard copy of the presentation to anyone, and I imagine the other two are probably not going to work either.

Oh, this one does work. Very good. This is a simulation of the effect of drying method. We have several parameters we can choose from, hot air drying, towel drying, or no drying, and what you can see is, again, since we're incorporating the underlying uncertainty and variability of the data, you can see that as we run this risk assessment multiple times, multiple iterations, we get a different effect each time, and so you can see the underlying uncertainty with respect to hot air drying, with respect to towel drying. You should notice that with towel drying, you have somewhat of a shift downward. That is, you get a greater log reduction with towel drying versus hot air drying.

This is looking at the effect of sanitizers, and we had some data available on alcohol-free sanitizers versus sanitizers containing alcohol. And again, you can see that there is a difference in terms of the variability, in terms

of the mean response and where the numbers lie generally over the whole curve.

So using graphs like these as well as some other ways of analyzing the data, you can look at the effectiveness of various choices in the hand washing system on reducing the number of bacteria present on hands at the end of the hand wash.

A few conclusions and implications from our work. Obviously, there are many factors that can influence the number of bacteria or number of microbes present on the hands at the end of the hand washing process. From our very preliminary risk assessments, some of the key factors seem to be the use of an antibacterial soap, ones containing CHG, based on the data that we've used, seem to show a greater effectiveness. Towel drying appears to be the most effective way of getting hands dry. And some sort of hand sanitizer reduces the number of bacteria on hands at the end of the process, as well.

In terms of future work, there's a number of things that we'd like to do to expand the work that we've presented here. We've started collecting some data in our laboratory on cross-contamination of faucet spigots that has been funded by Sloan Valve Corporation. We want to look at the effect of water temperature, the effect of wash time,

the effect of gloves, and also incorporate some way of dealing with resident versus transient bacteria.

Of course, as I've mentioned, it's very important to validate any sort of risk assessment. This is just a computer simulation. It's not reality. The results of that simulation need to be tested against reality.

Some final thoughts. While this risk assessment that I'm presenting to you today doesn't provide the answer yet, there are several key advantages, just to recap from my presentation earlier. The variability and uncertainty of the data are naturally included in the end result. So any decision that you make based on this risk assessment will have an inherent uncertainty associated with it. And also, very importantly, I believe that the data we used in our risk assessment are presented in a form that can be easily analyzed and explained. Somebody can take a look at the risk assessment that we've done here and see what our thought processes were in terms of how we link the nodes together, what our assumptions were, and what decisions we've made and what implications come out of that.

Finally, the quantitative risk assessment approach is useful because these risk assessments are expandable as more data become available. As I mentioned, we're currently involved in a study on cross-contamination ongoing in our

laboratory. It's taken us several months to collect some data, but actually, last night as I was sitting in my room thinking about this presentation, I was able to incorporate several key components of those data into our risk assessment. So within a matter of a couple of hours, I was able to expand the risk assessment to include new information.

This is what that revised risk assessment looks like. You can see this is the initial count that I showed you on the previous screen snapshot. This was the count after soaping the hands. This is the count after drying the hands. I've included several new chance notes. First of all, the hand-to-spigot cross-contamination rate, again, based on data collected in our laboratory. Also, the spigot-to-hand cross-contamination rate, again, from data in our laboratory.

We have also one new decision node, that is a decision node based on faucet type, either a traditional faucet where the user has to actually touch the spigots and then produce some sort of contamination on those spigots, and also a touch-free system where these cross-contamination rates would be eliminated from the risk assessment. So depending upon the type of faucet chosen, you have a faucet effect, which either will include these cross-contamination

rates or will exclude them from the risk assessment, and so now feeding into this node you have the count after soaping plus the effect of faucet type feeding into the next node in the risk assessment.

And again, this picture is created based on the way that we represented the data mathematically in our model, so as I change the risk assessment, the diagram was changed to match that model. I didn't use a computer graphics program to create this. This actually comes directly out of the risk assessment software itself.

So that concludes my remarks, and again, thanks for inviting me.

CHAIRPERSON WACHSMUTH: Thank you very much. Very interesting.

We have time for a couple of questions. David?

DR. ACHESON: On some of your earlier slides, you showed some data that would suggest that certain conditions are increasing the numbers of pathogens. Could you just summarize really quickly what those were?

DR. SCHAFFNER: That's a very good point. In some of the curves, you can see that the tails of the curves actually end up with a log change greater than zero, which is what you would expect--if you did nothing, you would expect to end up at zero. In some cases, we see a very

small tail right here. That reflects a number of different things.

In some cases, for example, with hot air drying, you can actually increase--there have been some studies that have been published that show you can actually increase the number of bacteria on hands.

Also, in all of the studies that we looked at, there was always some variability associated with the reduction. In some cases, that variability of the reduction of whatever that particular process was actually spanned the starting inoculum. So the data itself show some variability, again, a very small positive tail, but some positive tail.

As you run through the risk assessment, you do multiple iterations. That compounds itself. But again, that tail is there in the original data. It's small, but the effect is there.

DR. ACHESON: But that particular slide looks like alcohol is having a significant negative effect.

DR. SCHAFFNER: Well, you have to be careful in how you interpret these slides. This is looking at the effect of sanitizers in the context of the whole risk assessment. So there are other factors that are coming into play here that may be showing that. That may not be the

effect of alcohol alone because of the other factors in the risk assessment.

And one of the things that we're sort of struggling with in terms of how we present this is how you present the interactions of these different effects and make those sorts of points here. But it's a very good point.

CHAIRPERSON WACHSMUTH: Okay. We have time for one more question. Mike?

DR. DOYLE: I might just add, I think one of the important factors that need to be teased out in doing the risk assessment is differentiating the transient from the resident, as you indicated, and I think that's one of the effects we're seeing here with the alcohol sanitizer. We're seeing that we're affecting the resident flora, as well.

DR. SCHAFFNER: Right, and so what you see, as Mike just pointed out, what you see is you use that alcohol-based sanitizer, you're actually freeing up those resident bacteria and that's what's ending up in those counts. So that might not be a good thing from a hand safety, a hand care point of view. That's a very good point.

CHAIRPERSON WACHSMUTH: Okay. Thank you again, and we will try to have hard copies of the presentations for the committee members at deliberations tomorrow.

We've gained a little bit of time in questioning. I think we've had ten minutes of questioning, 15 minutes of questioning after the individual groups of presentations, so I think if we break now until 10:30, we can start our question and answer period about 11:15 and we ought to still be pretty much on track, so 10:30. Thank you.

[Recess.]

INDUSTRY PANEL

CHAIRPERSON WACHSMUTH: Thank you all. I hope you've noticed we have a new addition. This was kindly provided by our organizing staff. We've been asking for a bell. We now have a bell.

It's now time for the industry panel. Mr. Francis Ferko of the National Council of Chain Restaurants will start us.

MR. FERKO: Are you going to ding me if I go overtime? There you go. Okay.

Good morning. My name is Francis Ferko. I am Chairperson of the Food Safety Task Force of the National Council of Chain Restaurants. I'm here today representing the National Council of Chain Restaurants, which is a Washington, D.C. trade organization representing 35 of the nation's largest multi-unit and multi-State restaurant companies. Collectively, these 35 companies own and operate

more than 30,000 restaurant establishments, and through franchise and licensing agreements, another 50,000 establishments are operated under their trademarks. These members represent nearly two million employees throughout the United States.

Personally, with over 30 years' experience in various aspects of the food, retail, and manufacturing industries, I have degrees in microbiology from the University of Pennsylvania and an MBA from the University of New Hampshire. My background includes over two dozen years in quality assurance and food safety on the front lines. The first dozen of these years were in the food processing industry, supplying numerous restaurant chains and other food service establishments. During this time, I authored one of the first total quality assurance programs approved by the USDA. For the last dozen years, I have led the food safety and quality groups of several restaurant chains.

The reason why I provide the background is because in the early 1980s, the USDA had a problem and that problem was salmonella in roast beef, and what I'm going to present to you today, or what I'm going to leave to you today, directs to an alternate program, because the USDA had a situation where they had salmonella in roast beef, but at the same time, in the Northeastern and Eastern part of the

United States, there was a great desire on the part of the consumer to have rare roast beef. Ultimately, what was adopted, which also happens to be in the food code, were alternate cooking procedures, time and temperature. You recall 121 minutes at 130 degrees.

This is what the NCCR is recommending. Proper hand sanitation is the foundation of our industry. NCCR supports actions that assure proper hand sanitation. NCCR supports the minimization of direct contact of bare hands and ready-to-eat foods through the use of utensils, tissue paper, and, where appropriate, gloves. NCCR supports alternatives to the current food code requirement of no direct contact through programs like that adopted in the State of Florida, Texas, and California.

We believe that mandating gloving diverts attention from what should be our primary focus, namely, assuring proper employee hand washing and hand sanitation. It is illogical to suppose that failures in compliance with appropriate hand washing requirements can be addressed adequately by instituting an additional procedure, gloving, for which failures in compliance would likewise present a significant threat to the sanitary preparation of foods.

Our members have found that the best intervention between hands and food is through the use of utensils and

tools. As you can see from some of the items I brought here today, utensils have two parts. They have the part you grasp and they have the part that comes in contact with the food. This isn't rocket science, but basically, it creates an adequate barrier. They have two distinct parts. This assures us an absolute break.

The problem with utensils is that only so much of what you do in a restaurant can be done with utensils. You can ladle food, you can scoop ice, you can grab things with tongs, but there's quite a few of the jobs and duties that an employee has to do that cannot be done with tools.

For example, if you were to take a lettuce head, and you've probably all done this at home, if you were to take a lettuce head and you had to peel off the outside leaves, core it, and then cut it up, you can't do that with tools--maybe if you're Edward Scissorhands or something, but you can't do that with tools. Separating two halves of a--a very simple thing--separating two halves of a bun and placing them onto a toaster can only really be done with hands. Assembling sandwiches can only really be done with hands. You can do some things with utensils or tongs, but a lot of the things have to be done with hands.

So, ultimately, the issue, I think, that we have in front of us today really has nothing to do with utensils.

I think we all agree on that. I think the issue is, how do you manually handle food that you have to handle? What is the best way? And that's why most of the folks in the industry refer to the part in the FDA code as the gloving rule, because that's what the interpretation is.

In many instances, the use of gloves by food handlers has been assumed to be the solution. Here's a latex glove. I'll put one on to show how easy it is. Unfortunately, gloves do not provide the assurance of utensils and tools. In fact, gloves are not utensils. It is common knowledge that there are performance issues with gloves; I think they'll be shown today. There's an article published in the American Industrial Hygiene Association Journal where they said 85 percent of vinyl gloves and 18 percent of latex gloves that were tested leaked. There are numerous other studies, both published and unpublished, that confirm that gloves do not provide the same barrier as do utensils. They leak, they develop holes, they tear, and they may be used in manners that result in cross-contamination.

What gloves do provide is a false sense of security. The Journal of the American Medical Association in 1993 stated that many workers viewed gloves as a second skin. I think, ultimately, that's what most of us should

view that. We're replacing the surface of our hand with the surface of the glove.

Studies show that gloves were not changed as often as necessary, so actually, by wearing gloves, you can create a situation where there's less hand washing and, in fact, sometimes less changing of gloves. When compared to non-gloving, workers wash their hands twice as often when they didn't wear gloves as when they changed gloves.

The perception of safety enjoyed by the gloved food worker as opposed to the reality of how easily gloves can be contaminated may well have the effect of increasing the problem of noncompliance and of potential for cross-contamination. Observe for five minutes a group of gloved workers in a food establishment and watch what they touch with their gloved hands. Quite often, gloved hands are used for multiple tasks, and I think that's really the nut of the problem, is they're doing different tasks and when those kinds of situations occur, you really don't want to have gloves on an employee.

They are used for multiple tasks with limited regard to the issue of cross-contamination. Often, employees view gloves as designed to protect the employee rather than prevent contamination from the employee and prevent cross-contamination. One study published in the

Journal of Food Protection showed how gloves transfer infectious agents to employees, a cross-contamination issue.

In fact, I recently got a copy of the white paper by Jack Guzewich and Marianne Ross and on page ten of that report, even that report says that four of the 72 articles or the 72 reports specifically mention that food workers were wearing gloves when they had outbreaks.

So what are some of the other considerations in the use of gloves? Gloves interact with their environment and can become porous to microbes and viruses. Heat, mechanical action, cleaning and sanitizing compounds, and other factors combine to make gloving a problem. Some gloves are not effective barriers. I mean, you have the latex gloves, you have the poly gloves, you have very inexpensive gloves, and they all perform differently.

Survival of infectious agents can actually be greater on gloves, again, because of the lack of hand washing or the washing of gloves, which in most jurisdictions is prohibited or not allowed by the local health department.

Gloves cost dollars, and ultimately to the industry, we're really looking to do the right thing, the prudent thing, and we're looking for the risk reduction. If

it can be quantified, then I think the industry supports whatever needs to be done.

So when should gloves be used? Gloves should be used in restaurants for specific purposes. At a minimum, they must be available in every restaurant and used to cover wounds, minor scratches, cuts on the employees' hands that occur from time to time. Sanitary gloves should always be used to cover band-aids and wound dressing on hands.

But they need to be related to the tasks. Moving from task to task requires hand washing. Remaining at a task allows for glove use. You think of a house prep operation where the employee is taking a whole crate of lettuce and preparing it. That's a very good situation where a person can wear gloves. Other situations where they're going from one thing to another thing, that's a situation where they need to wash their hands.

When an employee is prepping a particular ready-to-eat item for a period of time, then gloves can be used. If an employee is involved in one task, they can wash their hands, apply gloves, finish the task, and remove the gloves before moving on to the next task.

I'd like to read to you some comments. These are quotes off of the Food Safe Archives, which is in public domain. Don't listen just to the industry but also listen

to the regulators. These are all comments by regulators, by health department regulators.

This first quote is from an environmental health sanitarian from Missouri. I quote, "Having watched glove usage across a wide spectrum of employee responsibility, I have to say the average person uses gloves in an irresponsible and potentially hazardous manner. While effective when used for a singular task, changed frequently, and used in conjunction with the regular routine of hand washing, gloves are often utilized as a magic barrier with infrequent disposal, multi-tasking, and inferior hand washing.

"The sensory deprivation of glove use robs the food handler of one line of defense, the feeling of food debris on their hands. Ill-fitting gloves have their tips cut off while slicing food products. Some users wear gloves in high-heat settings, such as grills and fryers and have caused injury when they melt, adhering to skin.

"One of my clients is a buffet service restaurant. They require their employees to wear gloves at all times. I fight a constant battle to see those employees change their gloves and wash their hands. They transport food. They fill containers.

"Gloves, like any other tool in food service, have their place. They are an augment to hand washing, not a replacement. Unfortunately, they lull food handlers and the general public into a false sense of security. The public perception is, gloves equal no risk. They should be selectively utilized according to the total benefit gained weighed against the hazards, in other words, using the right tool for the right job."

This is another quote from a local New York health official. "I understand that the New York State rationale from the beginning was to curb a Hepatitis outbreak in Syracuse, New York. This solution seems to have worked, yet I do wonder if it was a combination of increased awareness of the illness and means of spread as well as a concerted effort on the part of food services to implement proper hand washing procedures.

"I tend to agree with many other food safety professionals who believe that proper hand washing can effectively eliminate the contamination of food. Most economical gloves will not eliminate transfer of organisms through the porous surfaces, even if used correctly. I very often will recommend to food service personnel that they use utensils to handle food--spatulas--so that they will realize when their hands are contaminated and proceed to wash their

hands. Of course, then we get to the proper hand washing and the location of facilities and the temperature of water and everything else related to hand washing."

The last statement was published in the L.A. Times, and this is a quote. "Gloves don't do any good unless you change gloves often, each time you change tasks." That was a quote from William Ford, Assistant Director for Environmental Health at the L.A. County Health Department Agency.

A second quote was, "Food handlers wearing gloves are just as inclined to natural movements as the rest of us," added Jeff Lineberry, program manager for California's food safety program. "These movements include scratching at their face, using the gloved hand to wipe at something, or perhaps picking up something that's dropped on the floor. Gloves don't do any good if you forget you have them on." Again, that was Jeff Lineberry. End of quote.

So what's the alternative? I think the alternative is developing. I think you see it. It started, I guess--I don't know if it started with Florida or with the FDA, but there is an alternative and the alternative is to analyze each establishment, determine what the steps are to minimize direct contact, define those in a program, and then go forward and focus on hand sanitation.

If you look at the FDA food code, currently, it says that there be no direct contact unless otherwise approved and there is a section in the back of the book, it's Public Health Reasons, Section 2526, that talks about the requirements for having an alternative program. Truly, that information, which includes demonstration and knowledge, the duties that are done, the restrictions, the cleanliness, the hygienic practices, specific work areas, the actual food that will be handled and how it will be handled, job titles, training, hand washing and hand sanitation procedures, prevention of cross-contamination, illness, symptoms, and work exclusions and restrictions, should be available for each restaurant and each restaurant is different. Some restaurants have a lot of issues and some issues do not have very many issues because they're fairly simple.

CHAIRPERSON WACHSMUTH: Time to wind up.

MR. FERKO: Okay. So instead of a mandate on gloving, our focus must be on hand washing and hand sanitation. We must focus on assuring that all employees have an effective means of washing and sanitizing their hands. NCCR is not against the use of gloves. We believe they have a role to play in our goal of protecting our customers. We do believe and contend that the evidence

shows that gloves should not be mandated as the magic bullet. Hand sanitation is a complicated and difficult issue requiring a myriad of steps that include hand washing, the use of utensils, selective use of gloves, employee education, and management oversight.

NCCR believes the requirements for programs like the Florida model and the FDA model should be instituted in all jurisdictions and should replace the current requirement for no direct contact. Thank you.

CHAIRPERSON WACHSMUTH: It would probably be best if we had all three industry panel members and then we will get into the questioning period that will take us to lunch.

Our next speaker is Dr. Jill Hollingsworth. Jill is with the Food Marketing Institute. Jill?

DR. HOLLINGSWORTH: I'm not sure if you have a person to hand out materials. I left some up here. There's a copy of my presentation, if you want to hand that out to the committee.

Good morning, and thank you for the opportunity to meet with you today to discuss the issues related to bare-hand contact as it relates to ready-to-eat foods at retail. My name is Jill Hollingsworth and I am with the Food Marketing Institute and am here representing our 1,500 members who include retail grocery stores, supermarkets, and

wholesalers and their customers. Our membership is comprised of large multi-store chains, small regional operators, and independent supermarkets and grocers across the country and around the world.

For the record, I am presenting to the committee for its review a copy of the formal comments we submitted to FDA in response to the Federal Register notice. Also being passed out are a copy of these same comments that I'm reading to you today.

The scientific literature, primarily based on epidemiologic investigations, has demonstrated that food handlers can serve as a contributing factor in the spread of foodborne illnesses. Viral agents appear to be of a greater concern than bacterial agents. The premise that the use of a physical barrier, such as gloves or utensils, that would prevent the transfer of pathogens to food is an intuitively attractive idea. However, numerous disadvantages and complications are involved in the use of gloves or utensils as a barrier, and this is well-documented in the literature. Attached to the comments we submitted to the Federal Register is a bibliography of 226 articles regarding the effectiveness of hand washing and gloving interventions. I thought about reading those all to you today, but opted not to.

[Laughter.]

DR. HOLLINGSWORTH: Contamination of food is not caused solely by person-to-food contact. Pathogens may be transmitted to food from other foods, from the environment, and from other surfaces. Unfortunately, the very barriers that we may perceive as providing protection, such as gloves or utensils, may easily become the very surface that transmits pathogens to the food. In fact, in Fender's article, "Hand Washing and Gloving for Food Protection, Part 1: Examination of the Evidence," the authors concluded that the scientific evidence is insufficient to support the premise that the use of a physical barrier, such as gloves, prevents the transfer of pathogens to food. Such a conclusion cannot be reached.

I have followed this committee and its work over the years, and I must admit that it's a pleasure for me, and I'm sure it is for you, that for once, it seems that everyone has the scientific data and it has been presented. Unlike many of your other tasks that have been placed before you where you've been asked to make recommendations with minimal or limited scientific information, we think that that is not the case here. FDA has done a commendable job of compiling the scientific literature and soliciting comments on this issue. The bottom line is that when it

comes to protecting the public from foodborne disease, contaminated gloves and utensils are no better than contaminated hands.

Protecting the public from the transmission of pathogens from ready-to-eat foods at retail is no longer such a matter of science, because we have the science. It now becomes one of education. We often refer to pathogen control at retail as being an invisible challenge. Wearing gloves and using utensils may seem to be a solution because it is something visible, a visible sign that something's being done, but that is not sufficient reason to implement a no bare hand policy.

At grocery stores, we have a much tougher regulator than FDA or any State inspector. We have customers who watch everything we do every day. For many of the retail activities, we wear gloves because the customers expect it, and in many situations, they will demand that food be taken back and only handled by a person wearing gloves or using utensils.

But there are instances when clean, sanitized bare hands are the best method for accomplishing a task, and the scientific literature will show and has proven that this can be done without jeopardizing the public health. What is needed is a flexible policy that will allow operators to

determine the best method for the task at hand and making sure that there's minimization of potential hazards from contact with ready-to-eat foods.

The science clearly indicates that there is, unfortunately, no best way and no quick fix. The code should identify the hazard that we are trying to address here and present a variety of options that can be used to meet the goal. We further recommend that the Federal and State governments, academicians, and industry collaborate on an education campaign targeted to food handlers so that they will really understand the importance of this issue and the critical role that they can play in controlling the spread of foodborne pathogens.

One of the things I brought, and I'll also leave it here for the committee to look at, one of the educational tools that we've developed at retail are these small little cards. We call them quick tips. They are laminated. They can be washed off. They fit in a pocket. And there's a series of them on many different things, activities that occur at retail that affect food safety.

We have one here called "Guide to Employee Hygiene," and it quickly lists in bullet format reminders to employees about letting your supervisor know if they're sick, reporting exposure to infectious diseases, when to

wear gloves, how to wear gloves, and how to wash their hands. These are the kinds of educational tools that we believe will make a real difference in controlling the threat of pathogens and leaving the science where it is. that is, there is no perfect answer. All methods can have an advantage if they are done right.

Thank you for your time.

CHAIRPERSON WACHSMUTH: Thank you.

We have one more speaker in this panel, Mr. Steve Grover from the National Restaurant Association.

MR. GROVER: I'm Steve Grover and I'm with the National Restaurant Association here representing the association. I'm a former State regulatory official from the State of Virginia, President of the National Capital Environmental Health Association, and now Vice President of Health and Safety Regulatory Affairs at the National Restaurant Association.

One of the things I want to start off with in the restaurant industry is to tell you how important food safety is. Food safety is non-negotiable. All the illnesses that we heard about this morning happened either in a consumer's home or away from home, 100 percent. That's where people eat the food. People get sick either eating in their homes or eating in restaurants or eating at church events or away

from home. There are no other places. So everything that affects food safety is vitally important to the restaurant industry.

We have worked for almost three decades to develop innovative solutions to these problems, and they have been laid out here. I mean, you hear the problems. Now, how do we solve the problem? We have trained over a million managers in the principles of food safety. We have trained over two million employees in the principles of food safety, and we are not the only people doing training out there for the restaurant industry and other areas.

We have always worked to actively address food safety issues through the International Food Safety Council, for the Partnership for Food Safety Education, and through our support of the FDA food code. We truly believe that uniform science-based regulation is an important step in solving these problems.

Now, we heard the horror stories this morning. We've heard about the illness. How do we solve it? We're not opposed to glove use. What we are advocating is nothing new, and as was said earlier, it's been accepted by the three largest States. Florida, Texas, and California have all looked at this issue when they've done recent adoptions of their food code. The FDA absolutist view that you must

never touch food with bare hands, while I wish we could do it, cannot be done. It's unrealistic.

Having said that, we need to look for solutions. Generally, the idea of eliminating all bare-hand contact, while attractive to many, putting on gloves, while attractive as a silver bullet, are unrealistic for all the varied tasks that you have to come into contact with when you're working in a restaurant operation. We've believed for decades and have worked to improve hand washing compliance, because hand washing compliance and hand washing management is the solution to this problem and a balanced use of gloves.

One of the things that we've taken particular importance in doing is developing food safety training programs, and I've marked the section here. I'm going to pass this around. This is our Serve Safe program. As I said, we've certified a million managers in this and we continue to do more to try to make sure people get this training. I'll pass it around and you can take a look. There's a whole chapter in it on hand washing and glove use, how to do it appropriately.

Another effective tool that we've found is to try to make sure that the employees get the message through a variety of simple tasks on how to wash your hands, why is

personal hygiene so important. We have posters for the employee areas on why is it important, why should you wash your hands. We have these in thousands and thousands. We also have a little training program for the managers to mark the employees who were there and then to go over the important points of hand washing. I don't think we can overemphasize the importance of hand washing. These illnesses that we've talked about do happen and we have to address it, but we think we have to address it in a responsible manner that's effective.

Finally, this is our video, dedicated entirely to hand washing, how to wash your hands. Don't take it for granted. The people that we have coming into the food industry today do not have this basic knowledge and we have to train them and continue to train them, because, quite frankly, there is no other solution to this issue.

There is no absolute barrier. As we've said, the research has shown that gloves, out of the box, 60 percent leak, and I'm going to pass out some gloves here in a minute and show you why. The problem is, if the underlying hands aren't washed, then we haven't solved anything. People may feel better, it may look good, but it's not solving the problem. We need to address this problem directly.

There are no magic quick fixes. There are no silver bullets here. We need to address the hand washing compliance problem and the management problem by direct solutions. That includes education, training, and increased management.

Now, what I've got here, I brought some things for you guys to take a look at and I brought my lunch. One of the issues that keeps coming up time and time again is why can't we use gloves. Well, I'm going to hand you out some gloves to show you. I'm going to put these gloves on and show you why it's difficult.

Now, these are the most commonly-used gloves in food service today. Now, the problem is that you can probably sit here and write with your pen, and in about 30 seconds, there's a hole in it. Some of the science has clearly shown that once there's a hole in it, the sweat, the bacteria that grows underneath these gloves--in fact, they're a little hot, I can feel them already--will flow into the food. Some tasks, like the shrimp I'm going to eat for lunch here, are impossible to do.

So what the absolutist view does--and I'm not going to eat these shrimp, by the way--what the absolutist view does is it makes it illegal to do this operation. In other words, if I think that this creates a problem--well,

first off, I can't peel the shrimp very well. Oh, I tore the glove. I didn't get through one shrimp. Now, I've got 100 guests coming for dinner tonight and I've got to peel 500 shrimp and I tore it on the first one.

The problem--and I won't pass this dirty glove around, take it from me, we don't want to use this. I didn't get through the first shrimp and I've now got a problem because I've torn the glove and everything underneath is now all over the food. And, by the way, I'm not going to eat that shrimp. That will be one I won't eat. I'll peel them with my clean washed hands.

This is just an example of one problem, one issue we face. There are no silver bullets. There is no one-size-fits-all. What we have to do is train, train, and train again. There's no easy way to address this problem. This has been a problem that I've worked on my entire career, 22 years. I haven't changed my thinking on it in going from a State regulatory official to a President of the Environmental Health Association in this local area to working for the association. It has to be a practical approach. You have to tackle this problem directly.

That's the issue. That's what we're trying to do. That's what we hope to do. We think the FDA has gone a long way in including in Annex 3 of the food code the procedures

and management procedures to try to take this to a new debate, try to take this debate away from the absolutist view that gloves will absolutely protect us or that we can use tongs for everything or spatulas for everything, into a debate where we can directly impact this problem.

The good news is that many of the States have also adopted that thinking, California, Texas, and Florida, and we applaud those States for going forward on this.

That's all we're asking for. What we're asking for here is nothing new. It's been what we've been doing forever. It's working to address the problem in a conscientious manner that recognizes both clean washed hands and appropriate glove use. We're not opposed to glove use. Glove use has an important place in there. Limiting bare-hand contact has an important place, but you just can't do it all, either with the stroke of a pen or no matter how much we wish we could do. Thank you.

CHAIRPERSON WACHSMUTH: Okay. Thank you to all three members of the panel.

QUESTIONS AND ANSWERS

CHAIRPERSON WACHSMUTH: What I think we should do now is if you have any questions for Mr. Ferko, Dr. Hollingsworth, or Mr. Grover, we could take those first. Swami?

DR. SWAMINATHAN: Bala Swaminathan, CDC. I had two questions. One, on a recent TV program, one of these sensationalist talk shows that appeared to air between 10:00 a.m. and 4:00 p.m.--

[Laughter.]

DR. SWAMINATHAN: --they highlighted the problem of intentional food contamination with human excretions and excrement by disgruntled food workers, and I was wondering how significant this problem is.

MR. GROVER: Well, you're asking me to talk about how a gentleman who was just out and got struck by lightning on a golf course, for me to tell you how safe golf is. The problem is, these people were caught on camera, and the fact is, the fact that you need to know is they were caught. For them to do the story, they had to catch the people, and they were caught in the act of doing it.

There are a number of controls that we do in the food service industry to try to address the problem, through training, management, and through surveillance, and we don't catch a lot. There's not a lot. But does it happen? Yes. I mean, and lightning strikes happen to golfers on golf courses, too. But we need to be careful about making the unusual occurrence the norm. I would venture to say that the vast majority of our employees and the people that

operate our restaurants are as committed to your food safety as you would be expecting from your own family.

DR. SWAMINATHAN: The second question I have is, most of the educational materials that you have appear to be directed towards the managers and supervisors.

MR. GROVER: Those cards that I handed out and the posters and the video are all directed to the employees.

DR. SWAMINATHAN: How do you make sure that the managers and supervisors really train their workers, because we're talking about low-paid workers. There's high turnover. People do not speak English very well. How do you address all those problems and with all the things that the manager or the supervisor has to do in this food service establishment, how do you make sure that they give high priority to training of the workers?

MR. GROVER: You'll see, these are in two languages. We have translated this material in five languages. Number two is that that certification program that I told you that we've certified a million managers in has as part of it a training constituent for its employees, and how we've done that is the whole set of employees, you can see the manager training materials. We provide the manager with training materials and videos so to make it easy for him to do that.

Most food service operation training is the--you have to start from day one and you have to train continuously. There's training in food safety. The problem that we have in the restaurant industry isn't the fact that the training isn't happening, it's the focus of the training. If you train somebody to comply with 100 different codes every day, you have to continually reinforce what the most important codes are. We've got to do training in allergy. We've got to do training in safety. We've got to do training in slip and falls. We've got to do training in food safety. Sometimes, I think, the food safety gets lost amongst all the training programs that have to be done, and that's why we need to continually reinforce it.

We do it, we know that the leaders of our industry do it, and does everybody do it? No. Are we committed to helping everybody do it right? Yes. That's what we're here for.

CHAIRPERSON WACHSMUTH: Okay. Earl?

DR. LONG: Earl Long, CDC. Mr. Grover, I know that all food handlers are taught that they should wash their hands before touching food. Are they actually taught the mechanics of touching their hands?

MR. GROVER: In the programs that we have there, and as a matter of fact, we're moving our program beyond

when they come into the establishment. Sometimes, and the problem that we have, by the time they come into the food establishment, bad habits are already set up. We today basically have no program in the schools that is training people in some of these very basic things, and you know, whether you don't wash your hands in a restaurant setting or you don't wash your hands at home, these people who pass illnesses in restaurants, they're the same people who prepare food at home. So hand washing is important no matter where you go.

So we're working on an initiative right now through a Hospitality Business Alliance to bring these training programs to the schools, to get to people early, before the bad habits are established. But that doesn't negate the need for us training them when they come in the door.

And, yes, we go back to the basic, warm water, take them to the sink, and you can see. I mean, there's no rocket science here. This is wash for 20 seconds, lather it up with soap, and things like that.

DR. LONG: You've given the expected answers. Did you know that right-handed people do not wash the area between the left index and left thumb?

MR. GROVER: Did I know? I didn't know.

DR. LONG: Well, they don't, and I don't know whether left-handed people have the problem with the opposite hand. But you see people rub like this, so this area is left unwashed, or unscrubbed.

MR. GROVER: Well, we probably--one of the issues that we do--I think that we're working right now to make sure that we can get as much compliance as possible and that the next step would be probably to address those kinds of issues in these areas.

I would say that one of the things that we strive to do is to make sure that people rub their hands all over and lather it up entirely. So maybe we're hitting it, maybe we're not, but that'll be something for us to consider in future editions of our training program.

The problem is that in most cases--not in all cases--the people that we have coming into the industry are not Ph.D.s and it's going to be very difficult for us to explain that to them, about the mechanics of left hand versus right hand. We're actually trying to get them to wash their hands, starting with the warm water and the soap aspect of it. That's really the issues that we have at hand and the ones where we think we can make the greatest improvement in the overall sanitation in the establishment.

DR. HOLLINGSWORTH: If I can also add briefly to that, one of the things that I think is important is you look at our training and educational materials that we use for retailers, they are at basically three different levels. We take a tiered approach to training. One is for--it's like a train-the-trainer program, for people to get a much more training program that includes microbiological principles. Then there is a manager training, which is much more hands-on.

And then we have the employee training, which are more like the quick tips. They're short, they're easy to remember, they're repeated bullets over and over so people can remember them. We have a video that is also based on these tips. It only has four messages for the employee. It's quick and it's fast and it's the kind of thing that can be done at the store level because it doesn't take time and it's easy to remember.

Another thing I wanted to mention is that we are working very actively with the Partnership for Food Protection on the Fight Back campaign, and this month we're going to be releasing a whole new education campaign specifically targeted to fourth, fifth, and sixth graders, and it's a great program. If you hear about it or see it, you really need to look at it. It has games. It has things

that teachers and educators helped us design so that fourth, fifth, and sixth graders will really get these messages and carry them forward, hopefully as they get jobs and in their homes, and maybe even convince their parents to do some of these things.

The other thing, too, about hand washing that I wanted to mention briefly, is as we allow hand washing and emphasize the importance of it, one of the things that we have noticed is the new and innovative technologies that are being applied to hand washing. The Food Marketing Institute hosts a technology show, and one of the things that we have been impressed is the number of new innovations coming out in hand washing, automatic washers and sanitizers and those kind of things, that if hand washing is emphasized and the importance of it is made, I think the technology will keep pace and even go beyond what we do today.

CHAIRPERSON WACHSMUTH: Thank you. Michael, just a second. Has this adequately answered your question, Earl?

DR. LONG: It was just something I thought was worth mentioning.

CHAIRPERSON WACHSMUTH: Let's go to the next question, if it's okay. Michael?

DR. JAHNCKE: Michael Jahncke, Virginia Tech.

CHAIRPERSON WACHSMUTH: Just raise your hand. I think that will turn you on.

DR. JAHNCKE: Mr. Grover, my question is, as you are aware, education programs are important, but it's really the implementation of these that make it effective or not. What type of programs do you have or schedules do you recommend as far as follow-up type things and what do you have in place as far as evaluation of the effectiveness of your various training programs?

MR. FERKO: Evaluation of what?

DR. JAHNCKE: Well, if you provide the training to your supervisors, your employees, through videos and all these, do you have any way of evaluating how effective these training programs are for the employees and the supervisors?

MR. FERKO: Each member of the NCCR, each company has a different process they go through. Some use self-inspections of their restaurants. Some use other forms of measurement devices. If you look at HACCP, step seven is verification, and most of the chains have those kinds of programs they go through.

The real important thing here is that we have to make it easier for people to do the hand washing at the point they need to do it, so everybody is doing different things in order to see what is the optimal system. Again, a

lot of what Jill was saying was that looking at new technologies just to make it more easier or more inviting for the employees to wash their hands.

CHAIRPERSON WACHSMUTH: Does that answer your question?

DR. JAHNCKE: Yes. The other question is, what as far as recommendations, as far as your follow-up on training? You give initial training to new employees and supervisors, but people come and go. People forget. I'm just wondering, are there any standard protocols or recommendations as far as follow-up training?

MR. FERKO: Most companies do the training when the employee first gets there and then they have to basically repeat it every so many weeks. They also, if you have a general manager in charge of a restaurant or a manager in charge of a restaurant, they're observing the employees to see whether they do hand sanitation like they do other things. Some companies also, like I said, use outside services or use internal people that evaluate their system to see what their compliance rates are.

CHAIRPERSON WACHSMUTH: That wouldn't be like an objective evaluation. I think that was what the question was about.

DR. DONNELLY: I'm wondering if any of you could comment on policies and procedures that you have that have worked that encourage ill employees to not be handling the foods. The whole issue of ill workers being in contact with food, could any of you comment on policies and procedures that you have in place that provide incentives for ill workers not to come to work, or how do you manage that whole issue?

MR. GROVER: I can only--I heard a question earlier today about how many establishments offer sick leave or even health benefits to their employees, and I can tell you through our surveys, which is surveying our membership--now, I know that there are some problems with surveying our membership because we feel that our members are the leader of this industry, but almost 50 percent of them do offer sick leave and benefits to their employees.

So I don't know if the folks that are doing the epidemiological after-the-fact investigations are just running into the bad actors or running into the establishments that don't have this policy, but clearly--and that's up. That's significantly up, and clearly, it's one of the issues that we're challenged in attracting and retaining top-notch people. We just, quite frankly, have to offer those benefits today, and that is happening. So

from that aspect, I can tell you that our research is showing a great improvement in that area.

MR. FERKO: I think it's an issue when an hourly employee comes in to work and they're ill and they have to be sent home. Yes, they do lose that money. Most managers will try to make it up to them at a later date, but that's just part of the situation.

CHAIRPERSON WACHSMUTH: Okay. Do we have another question?

DR. ANDERS: Yes. This is Jim Anders from the Health Department of North Dakota. I'd like to address the issue of permeability of these gloves. We wear, in our facility, we wear gloves all the time. We would never wear something quite like this. I personally think this is not very good, and obviously, you showed you had holes in it.

But the question really becomes that there are gloves that are available, first of all, that would fit better than these--

MR. GROVER: Mm-hmm.

DR. ANDERS: --and secondly, that are better. There are some new ones out and there has not been a whole great deal of research yet on those, but called Index, for instance. They're a nitrosynethic. They're actually

puncture-resistant and they are very difficult to actually cut holes in them or to use mechanically.

So I guess one of my questions, my big question, then, is that it doesn't seem like they're using very much money within the industry to look for gloves that might be puncture-resistant. I realize that there are other problems with gloves, but I'm specifically addressing the puncture part of it and the holes in them. It seems to me that there are some other alternatives out there.

MR. FERKO: I think we agree with you. I think if you do specify gloves, you need to specify which ones.

CHAIRPERSON WACHSMUTH: Mike Doyle, did you have a question?

DR. DOYLE: This is Mike Doyle again. This is a question for the panel. The common theme I've heard is that, intuitively, it's best to use gloves at certain times and it's best to wash your hands at other times, but do we have scientific data to support when we should be using gloves versus when we should be washing our hands?

I have a good friend who once said, when a food handler uses the restroom, it's best that he puts his gloves on when he goes into the restroom and takes them off after using the toilet. Well, intuitively, that makes a lot of sense to me, but I don't know that that's a common practice.

Have you done the research? Do you plan to do the research? I think as you make these recommendations--handling coins, for example, can that be a problem? Should we wash our hands before handling food or do we need to glove ourselves after handling coins and then handling food? I mean, there's a lot of questions out there in terms of what food handlers are doing. Do you have the data to support which way we should be going?

MR. GROVER: Oh, I believe on the handling coins issue, FDA has done the research and did come out and say that it was fine, and we would recognize FDA's authority on that, and they do have an interpretation on the handling of money. I don't know if it's still valid, but they clearly did look into that issue and we recognize their interpretation on that.

As far as the research is concerned, I could throw it back and say, do you have the research to show that gloves in restaurant settings are safer than clean washed hands, and the answer is no. Unfortunately, there's a lot of problems with this scientific debate, and you can throw it back and forth and say the research isn't there, the research is there.

What we're saying is, there are no silver bullet solutions. There are no one-size-fits-all. There are

problems with everything, and that if you take a common sense, logical approach to it, using gloves where they're appropriate, using clean washed hands when they're appropriate, we can probably address this problem. Will we get to 100 percent? I'm not sure. I don't think so. And that's it.

MR. FERKO: I think you divide the tasks up in the restaurant and there's a group that go to utensils, there's a group that go to gloves, where you're doing one task at a time, and then the issue is on those remaining tasks where you're going from one thing to another.

CHAIRPERSON WACHSMUTH: Okay. Michael?

DR. DOYLE: But my point is, I think we need more data than what we have and I think it should be incumbent on the industry, before suggesting we do it this way or that way, to do the science, to do the studies so that we have some hard data that we can relate to.

CHAIRPERSON WACHSMUTH: Dr. Kobayashi? I've got a list.

DR. KOBAYASHI: It seems to me that while there are many, many outbreaks reported in the literature related to foodborne outbreaks and ill food handlers or contamination through food handlers, that one of the main lacking areas is sort of having the denominators along with

the numerators. My question is for any or all of the folks that have presented. Is it possible to get information about your associations on specific interventions that were uniformly implemented by your membership so that we could compare, say, those restaurants where there was some sort of policy of administering sick leave within your restaurants and compare those restaurants who offer sick leave and those who do not to see if it makes a discernible difference on how many outbreaks are related to people who are still working while ill? Is it possible to gather that type of information through your associations so that that can be compared with the occurrence of foodborne illness that the CDC might have?

MR. GROVER: There are a number of problems scientifically with that. Number one, we all know that the foodborne illness is not evenly distributed and one outbreak could make one place look worse. I mean, Hepatitis, most of the foodborne illness, E. coli, is not evenly distributed in either regions or areas.

Number two is, I think the basic question is how many people didn't get ill, and I don't know if we will ever have a good number for that.

So there's two problems, not that it couldn't be done, but there are serious problems with trying to develop

and then rely on that data. Even CDC in its latest estimates, which are better than ever, admit that over 80 percent are from unidentified causes. Eighty percent of the foodborne illnesses they report are from unidentified causes. So, clearly, they've spent millions of dollars and a lot of time and effort to try to look at this issue and we still don't have the kind of definitive data that we would all like.

But do we want it? Yes. Will we work on it? Yes. But there are a number of problems in foodborne illness, foodborne illness reporting, and identifying the cause, and I'm not sure that we're going to have that information any time soon.

CHAIRPERSON WACHSMUTH: I think this question did open it up, and it's about that time, as well, open it up to the previous speakers. Is there anyone in the other panel or other two panels who would like to answer this question? Okay. Bill?

DR. SPERBER: Bill Sperber, Cargill. Speaking of the need for data, I wonder, in the restaurant industry, what is the rate of compliance with hand washing requirements?

MR. FERKO: There is a--I think a lot of the restaurant chains have done studies internally, but I think,

for obvious reasons, there are issues of making that information public because, basically, everybody's trying to improve their percentages. I mean, we have employees that come into our restaurant who are folks that we have to continue to work on to do a better job. I've stood in a restaurant and observed the frequency and seen one restaurant, I would say, is at 100 percent, and another restaurant might be at 50 percent. I think it just depends upon the individual restaurant.

MR. GROVER: And I would also say that the compliance with hand washing across all segments of the industry, people that cook at home and in institutions, is probably similar. Hand washing compliance in our society is not that good. Even physicians, and there have been some studies on physicians, aren't washing their hands properly all the time. So that just means we've got a lot of work to do.

CHAIRPERSON WACHSMUTH: Do you want to finish, Bill, and then we have quite a few hands, so--

DR. SPERBER: I have one little follow-up on that. A couple of years ago, at the American Society for Microbiology Annual Meeting, there was a survey of observing microbiologists using the restroom and how many of those washed their hands, and I think the compliance rate there

was 60 or 70 percent, which is a staggering number for professional public health people.

So one point that bothers me in this whole discussion is that if we have trouble getting compliance with a basic procedure like washing your hands, I think we'll have the same problem with any glove procedure, because using gloves, as we've already heard today, is not easily done effectively.

CHAIRPERSON WACHSMUTH: David?

DR. ACHESON: David Acheson. Mr. Grover, you mentioned that the States of Florida, Texas, and California, from what you said, have adopted some middle ground here. Could you explain to me exactly what it is that they have gone for, and also whether this has had any impact on foodborne diseases in those States versus ones that are doing different things.

MR. GROVER: What Florida, Texas, and California, the three largest States, have done is basically worked with industry, and they recognize--Florida actually went in and developed a hand washing management protocol, and California basically spelled out when hand washing is critical and things like that.

And what we did is we sat down, actually, with all of those States and worked out something that is not quite a

silver bullet. It's not a silver bullet here. But what it does is it focuses on hand washing as what we need to solve and then appropriate glove use. And so it's a middle ground.

Now, I have all three of those and I can bring copies--I have the copy of the regulations in all three States with me here today, so I can give those to you afterwards, but I don't want to read the regulations up here. They're rather quite lengthy. But we can submit those and then you can take a look at where they are. But they all have come at it a little differently.

The problem is that what we would like to see from FDA is leadership on this issue, to set a uniform standard that all the States could adopt as sort of that middle ground, as sort of recognizing the importance of hand washing.

And I think what we're saying is that clean washed hands, as long as we work to make sure that we do a better job of compliance and we do a better job of management for that, clean washed hands pose little or no risk. It's not the bare hand, it's the dirty bare hand that's a problem. I think that in working with these States, we found a way to protect the public health and to be reasonable, have a reasonable approach, not look for a one-size-fits-all. And

I can give you the copies of them, but the details, they're all quite different in how they've come around to it. But the effect is the same.

MR. FERKO: I have a copy of the direct hand contact compliance manual for Florida which we can make copies of and provide to all the members.

MR. GROVER: It basically goes into a lot of details on how to set up the system.

CHAIRPERSON WACHSMUTH: Okay. The list that I have is Mike Robach, Stephanie Doores, Alison. Mike?

DR. ROBACH: Mike Robach with the County Group Companies. Coming out of the food processing industry, it seems to me that the goal we're trying to achieve here is to minimize the public health risk associated with the handling of ready-to-eat foods. In that, it seems like it's more of an issue of food contact-surface sanitation to me. Regardless if it's hands or gloves or utensils, countertops, boards, whatever, I think we have to be looking at the result here and individual operations are going to have unique needs which will require them to take into account different technologies and different strategies towards achieving this goal.

I would assume that the industry, as it looks at food contact-surface sanitation as part of their daily

regime, should take on the idea of handling, whether it's with gloves or whether it's with bare hands, in the same manner and focus on the washing and the sanitation of those surfaces. I would just like a comment from the panel in that regard.

MR. FERKO: NCCR basically agrees with that. We believe that each particular situation requires its own evaluation and own work to minimize cross-contamination from whatever surface. Obviously, utensils are probably the nicest system because usually you put a ladle inside the food or you put the tongs inside the food, so that's easy, but it's everything else that's the problem.

DR. ROBACH: One quick follow-up to that, too, and then, Jill, you can respond to that, as well. Part of that all, and I've heard the word HACCP thrown around a few times in the discussion this morning, and obviously, incumbent upon that approach is a recognized verification and validation procedure so that you know the strategy that you're employing is effective.

DR. HOLLINGSWORTH: I agree with your comments, Michael, that, in fact, I worry sometimes that we're focused too much on the means and not the goal, and that was one of the points that I was trying to bring out, that what we really need to focus on is what is it that we want to

achieve and what is it we need to do to give operators and retailers and restaurants the opportunity to achieve the goal, and I think they're in the best environment, they're in the setting where they need to make that determination. If gloves are going to work, then let's use gloves. If hand washing is the best thing, let's use hand washing. But I think we need that kind of flexibility, because just one answer doesn't always work.

I would also, if I could briefly go back to the issue that Mike Doyle raised, and that is the one of science, we feel that the science is pretty strong in, first, identifying that there is this problem, secondly, that hand washing can be effective but it can also be very bad, that gloves can work but they can also be bad. So what we're trying to focus on in the area of data, I guess, is more soft data and that's behavioral issues--how do you change behavior, how do you modify it, how do you monitor it--as opposed to hard science.

If the committee feels that there is more science that's really needed, then I think we would be open to listening to what kind of science is needed as far as the hard science. Our focus right now is on the behavioral issues and how do we change that and make those changes come about.

CHAIRPERSON WACHSMUTH: Okay. Stephanie?

DR. DOORES: I know you pay a lot of attention to things like cuts and open sores on hands and that would be an appropriate time to wear a glove. How does the restaurant industry view acne, especially in light of having a lot of young workers in restaurants?

MR. GROVER: Well, in our program, you need to understand that the managers are not capable of making a diagnosis, so any open cut or wound on the hands is viewed--I mean, they're not going to know whether it's acne or a sore or whatever. Diagnoses are never made in the restaurant. We wouldn't know what it is. But if it impedes or it's on the hands, then it has to be dealt with, either through moving that employee to another job or no direct bare-hand contact.

Now, on the rest of the body, it becomes a different issue and there are other conflicting laws that would deal with whether we can actually take any action there or not.

DR. DOORES: Certainly, on the face, you could have a lot of hand contact, touching acne.

MR. GROVER: You could, but it's not on the list of diseases transmittable in the food from CDC and we'd be in trouble under the Americans with Disabilities Act. We

actually would need to get more science on the transmissibility in foods.

DR. DOORES: But one of the things, if you look at the guides for when you should wash your hands and change your gloves, includes when you touch your face or mouth, so that is listed as a reason for cause to rewash your hands or change your gloves.

CHAIRPERSON WACHSMUTH: Alison?

DR. O'BRIEN: Yes. I'd like to revisit the question that Dr. Acheson just asked because you did not answer the full question. Maybe you don't have the data.

The issue of, has there been an impact by the procedures enacted in Texas, California, and Florida. Now, we already--may I finish the question? We've already heard that in New York, where there is a no bare-hand contact ruling, that at least for Hepatitis, as I understood it, there has been a decrease in incidents. Why isn't clear, but there has been. So I'm wondering, are there any data among those three States or any other State that has taken either the middle ground or the ground of no bare-hand contact on foodborne illness?

MR. FERKO: I don't think we're--

MR. GROVER: I don't think we're in agreement on New York, either, based upon CDC FoodNet data, that it's so clear that the--

CHAIRPERSON WACHSMUTH: Microphone.

MR. GROVER: --the annual incidences of foodborne illness have actually been decreased in New York. I don't think--

DR. O'BRIEN: That's not what I heard the other gentleman say.

MR. GROVER: That may have been what was said, but I don't believe that under FoodNet data that that's clear at all.

DR. O'BRIEN: That's not what he said. He said the incidence of Hepatitis in an area.

MR. GROVER: Hepatitis or any foodborne illness in New York State.

MR. FERKO: That was a quote from a regulator who said they assumed that was the impact, but they weren't necessarily sure that it was that or just the increased attention that the problem had done. Is that what you're referring to?

CHAIRPERSON WACHSMUTH: Dale, do you want to comment? You can come up here.

DR. MORSE: New York is an EIP FoodNet site. The data presented were on foodborne outbreaks, which clearly showed a decrease in the total number of outbreaks and outbreaks associated with food workers since the no-hand-contact rule. Also, we have not seen a documented outbreak associated with a food worker where it had been documented where they had been wearing gloves.

The data you're referring to in FoodNet is surveillance for individual cases, which are not necessarily associated with foodborne outbreaks, and New York is a participant in that. New York has only been participating a year and a half, so we don't have the longitudinal information to compare data on Campylobacter, Salmonella, Shigella over time.

MR. GROVER: But the difference with other States who have the more middle ground regimens, I don't see any difference between the outbreak rates in New York as to the other States.

DR. O'BRIEN: Do you have any data?

MR. GROVER: Yes, CDC FoodNet data that was recently released.

DR. O'BRIEN: I'm talking about food handler-associated outbreaks.

MR. GROVER: No. I don't have any data on that. I don't believe CDC has any, at least that's been released at this point.

DR. O'BRIEN: Okay.

DR. MORSE: So FoodNet data doesn't address this. I guess that's--

MR. GROVER: Not in specifics, only in general foodborne outbreaks.

CHAIRPERSON WACHSMUTH: Okay. Roberta?

DR. MORALES: Roberta Morales, RTI. I guess I have a couple of issues I see here. One is implementing these safeguards such as hand washing and gloving. But on the other hand, I also see that there's something of an issue with whether or not there's adequate facilities to provide ease for the hand washing, the gloving, and things of that sort.

The questions that I have are, does the industry actually have provisions currently to ensure that there are adequate facilities and equipment to provide ease for the hand washing or the gloving, adequate amounts of gloves, sinks that are close by, things of that sort? If so, what are those provisions and what do they consist of?

I'd also like an opinion from the panel as to whether or not you feel those current provisions are

adequate, or if they could actually be improved so that there was more of a way to ensure that there was adequacy of the equipment and facilities to allow implementation of these safeguards.

MR. FERKO: I think the facilities basically consist of a functional hand wash sink, 110-degree water, antibacterial or non-antibacterial hand soap, paper towels or a hand dryer, and in some cases, instant hand sanitizer of some type. Also, the FDA took it out of the food code but quite a few of the restaurants still have a standard to use nail brushes, at least at one back-of-the-house sink, and they put that in sanitizers. Those are the facilities.

I think what we're talking about is you can provide--it's like seat belts. You can provide the facilities, but if you still don't get the employees to do the behavior that you want to, then you have to look at what are the other things, what are the behavioral things that help them, and that's why people are working with touchless faucets, they're working with sensors that measure when an employee washes their hands to kind of determine if there's that one employee who's your problem employee that you need to spend more time on.

All the different companies have different programs to try to accentuate and increase the frequency of

hand sanitation with their employees. I don't think there's any absolute. I think there's different things for different building designs. There's different requirements. If you had, for example, a large white tablecloth restaurant, there might be different requirements than, say, a small sandwich shop where there would be one or two employees.

MR. GROVER: Yes. I think one of the issues that we would like to use to address this is the FDA food code. The food code does address this issue and the Restaurant Association supports the nationwide adoption of the FDA food code. Even the previous editions under 1976 included this requirement. The problem is, there are 3,000 State and local entities out there and enforcement and training at the local level amongst the regulatory folks is extremely variable. When I see things like, "didn't have a hand sink," I'm wondering, where is this, you know what I mean?

You will see in our training materials that we strongly encourage hand sinks, but, of course, compliance with our recommendations and our training is voluntary. We would strongly say that there needs to be a uniform food safety principles and guidelines, which includes an adequate hand sink and proper number of hand sinks in the

establishment. We've worked with FDA. We've worked with State and locals to make sure that that happens nationwide.

So we would like to see an even playing field there, and, yes, that there be adequate facilities in every establishment that serves food. Now, remember that not all of those are restaurants. A lot of them are institutional. Some of them are temporary events, where laws have been put forth that don't require adequate hand washing facilities, and we would say that those should and that we'll work to make sure that the laws and jurisdictions and that the requirements in all jurisdictions in the country are similar and uniform as far as making sure that these facilities are available.

CHAIRPERSON WACHSMUTH: Jim?

DR. DICKSON: Jim Dickson from Iowa State. Can you comment from either an industry or from a regulatory perspective on what are the results of a lack of compliance. I guess it seems to me that we've got a couple of different interventions out there right now, whether it's gloves or hand washing or whatever, but it's all based on whether people use those interventions. What if they don't? What is the industry perspective? What is the regulatory perspective? I guess it really comes down to enforcement. What happens?

MR. GROVER: Well, I think it's quite simple. What happens when they don't is what we saw this morning. Illness happens, and you have to understand that no matter what the ultimate cause of that illness is, restaurants are damaged by it and the industry is damaged by it and it's not in our best interest. So the result is illness, and one foodborne illness is too many on this issue. So we're going to have to keep working on it until we get it down there.

DR. DICKSON: If I can add one--

DR. HOLLINGSWORTH: Jim, I think to address your question further, there are inspections at all retail establishments and they will be written up as deficiencies. Now, it's going to depend on the local or State code that they're operating from, but those kind of violations are reported and it varies from place to place. It varies from store to store. I would say what I see as the ultimate, we have certain stores within our organization that actually have a policy that if an employee personally does something to cause a store's rating to be lowered, they're terminated.

So there are some policies in place and there are some very strong programs in place where the consequences are laid on the employee if, in fact, they will not comply. A lot of them are given one chance. They are given a second

chance to learn. But if they can't do it, then they can't work there.

DR. DICKSON: I guess that was really the basis of my question, is what are the proactive stances that are being taken as opposed to a reactive stance, that if something happens, then we go in and address the problem. What are we doing in advance? What proactive stances are out there? Thank you.

CHAIRPERSON WACHSMUTH: Okay. I want to make sure that the committee is addressing questions to--well, before Diane goes, let's open it up, make sure if you have questions for any of the other presenters on the background issues or in the epidemiology, feel free to ask those questions now. We have about ten more minutes. Dane?

DR. BERNARD: Thank you. I was just curious as to whether we are going to get a copy of Dr. Morse's slides, because we don't have much data, but what we do have seem to be partially captured, at least, in Dale's slides, so it would be good, I think, as we go through our deliberations to have a copy of those. Thank you.

DR. MORSE: They are being made.

CHAIRPERSON WACHSMUTH: Yes. The answer is, we'll have copies for committee deliberations. Dave?

DR. ACHESON: I have a general question, as to what precisely is the definition of a food handler. Is a bartender who puts a piece of lemon in a gin and tonic, is that a food handler? We saw an example this morning of how that can occur. Or somebody puts a cherry in a drink, is that a food handler? Where does it start?

MR. GROVER: Well, there's food handlers in your home. You're a food handler and so are the people that work in establishments that directly contact food anywhere. That's our definition. Anyone who directly contacts food is a food handler.

MR. FERKO: I think there's some debate on the case of servers of when they're a food handler and when they're not. If they're just bringing plates and glasses to your table, are they a food handler? I think the consensus now is, as long as they're not actually touching the food itself, they're not a food handler.

CHAIRPERSON WACHSMUTH: Earl?

DR. LONG: Earl Long, CDC. We focus very strongly on the transmission of pathogens by the food handlers' fingers. I was wondering about other parts of the food handlers' body, like hair, for example, with Staph aureus, or saliva, and I don't mean spitting into the food, but just

speech. Saliva gets out. I was wondering about the transmission of Hepatitis this way.

MR. FERKO: I mean, all the requirements have a hair restraint or a head cover of some sort. I don't think anybody's gone to masks yet to cover the mouth and the nose. Maybe that's the next step; who knows. But every jurisdiction pretty much says that if you're working with food, you have to restrain your hair so it doesn't get into the food itself.

CHAIRPERSON WACHSMUTH: Dan?

DR. ENGELJOHN: Dan Engeljohn with USDA. What conditions of illness would I need to report to you if I were a food worker? Do you have a list of those that you follow in what you provide your constituents?

MR. FERKO: I think the standards are specified in the FDA food code. At least, that's what most of--probably all of our companies have adopted. Basically, when you're talking to an employee, you basically explain to them the symptoms that you want them to tell you about, and if they go to a doctor and the doctor gives them a fancy long name, you want them to tell you about that, too, because half the time they can't repeat it anyway. So you're talking really kind of gut-level here of having your employee let you know when certain things occur, and then it's up to the manager

to try to sort it out and figure out if it's something that they need to exclude them or not exclude them.

CHAIRPERSON WACHSMUTH: Smiling at gut level. Craig, did--

MR. GROVER: Dan, you'll see in our training program. Oops, I'm sorry.

CHAIRPERSON WACHSMUTH: Did Craig Hedberg have something to add to these? I noticed you were standing.

DR. HEDBERG: I was just getting ready to jump in.

CHAIRPERSON WACHSMUTH: Being prepared. Okay.

MR. GROVER: Dan, you'll see in our training program that 90 percent of the time in the restaurant environment, we don't get a diagnosis first. You get a symptom first and you have to deal with the symptoms, not a diagnosis at that point until the doctor sees the person and makes a diagnosis. Our restaurant managers are not trained to do diagnoses. Actually, knowing the illnesses are not as important as knowing the symptoms that are incompatible with food service.

MR. FERKO: Yes. A manager doesn't determine whether the vomiting is caused because they had a big night out the night before or whether they have a foodborne illness. They just need to get them out of the restaurant.

CHAIRPERSON WACHSMUTH: Mike?

DR. JAHNCKE: Mike Jahncke of Virginia Tech. I want to jump back to an earlier question, to your training programs. Emphasizing the training is primarily one of your strong focal points as far as in the restaurant industry. The material that you passed around, is it my interpretation that this is a standard training program or do different associations and different industries, I assume, have their own training programs, but how standardized is the training material that you passed around?

MR. GROVER: This is just one of them, and it's the most widely-used one, but there are many others, and there are individual corporate programs which are either based on this or exceed this in many areas. So this is just one example, of which there are many, based on these same principles.

DR. JAHNCKE: Do you have--oh, I'm sorry.

MR. FERKO: There's also regulatory programs in certain States and municipalities that require the employees or the managers to come in for their version of the training.

DR. JAHNCKE: It gets back to evaluating these training programs.

MR. GROVER: There's a national certification right now. This is a certified program and there are two

others we have strongly pushed through the National Conference for Food Protection to make sure that all food safety training programs meet a national standard. Yes.

DR. JAHNCKE: Thank you.

CHAIRPERSON WACHSMUTH: David?

DR. ACHESON: Are you aware of any restaurant chains that offer Hepatitis A vaccination to their employees or recommend that?

MR. GROVER: We actually have a program which offers discount vaccinations onsite which our restauranteurs can access with a phone number. The problem with Hepatitis A, for one, it's not evenly distributed, neither geographically nor age groups. So you need to look--it's a business decision based upon the part of the employer. There are--Branson, Missouri, actually did do it. Hepatitis transmissions amongst the whole world of Hepatitis A transmissions are extremely rare in food service operation.

The problem is that you need to make sure the community that you're in, is it good sense for your business, and then we advocate it as use of insurance. In other words, if you're in a community where you have a high incidence rate, if the age group of the outbreak is in your employees, then it's a good factor to look at from a restaurant standpoint if it's good in that point. But there

are other parts of your restaurant chain or other areas where they haven't seen a Hepatitis A outbreak in 20 years. It makes little sense, and I think CDC has agreed with us on that view, that mass inoculations are not appropriate. However, case-by-case is a much better way to look at that Hepatitis A issue.

MR. FERKO: I think NCCR members have taken the steps in certain areas. Rivers and drainage and delta basins, that kind of areas, a lot of the companies have gone through intervention steps. But as Steve said, as a general, let's give everybody shots, I don't think so.

CHAIRPERSON WACHSMUTH: Swami?

DR. SWAMINATHAN: Bala Swaminathan, CDC. This morning, Dr. Dale Morse appeared to suggest that certification and recertification for food service personnel might be something that's worth considering. He didn't come out and say so, but at least he pointed out, in New York, lifeguards are required to be certified and have to undergo recertification, whereas the food service workers are not. Would the panel like to comment on that?

MR. GROVER: Well, I think our program speaks for itself. I mean, this is something that we highly recommend that all restaurant managers, in fact, all employees, have access to and use. The problem with giving that over to

another entity to enforce is that they start to dictate what program needs to be used and we think that industry-developed programs are the ones that have the greatest chance for success and the greatest chance to meet these problems. We're the ones that have to make them work, and mandated programs sometimes don't always meet these criteria, nor are they nationally accredited or certified, and that's been our experience.

DR. HOLLINGSWORTH: One of the things that we have seen is a trend toward States requiring that there be a certified food manager on every premise. So those States that have that requirement, we do meet that. Those managers do need to be trained and certified according to a national accreditation program. It is not required in all States yet. Nevertheless, we have a lot of retail members who meet that standard anyway.

I think that the real issue and the challenge is how low a level can you bring that kind of training and certification. The idea of having every person in a store who ever handles food to be certified is a great concept. It would be extremely difficult, primarily because of the high turnover rate, but that doesn't mean for those employees who have shown that they are doing this as a

career and that they have longevity, that it might be a good approach.

MR. FERKO: A great majority of the chains have training programs and require their managers to be certified through some organization, Serve Safe or some other kind of thing. Depending upon the size of the organization, they may go down through the submanagers, assistant managers, or kitchen managers.

I think where the debate comes in is the individual employees. What do you have them do? Now, one of the things Steve didn't talk about is there's also a subset of the Serve Safe program that's an employee guide that quite a few of the companies use as a training tool to train their employees. As you're training the managers, you want to make sure that the employees know the same thing, but just in a more simplified fashion.

CHAIRPERSON WACHSMUTH: Skip?

DR. SEWARD: Well, that got answered three times, but I just wanted to say, I think that comment about the State of New York and the certification was more a reflection on the State of New York than on the food service industry or food handlers, because as these people have indicated, companies have their own programs. For example, McDonald's, where I work, we require that all shift-ready

managers be certified in Serve Safe so that you have a shift-ready manager who's qualified and understands food safety as per the Serve Safe program.

I didn't want that point to get lost there, that that was somehow a reflection on the industry, that they were not certifying their employees. I think different States have different regulatory requirements for manager certification, and that's what we're really talking about here.

CHAIRPERSON WACHSMUTH: Okay. Thank you very much, panel.

It's a little after noon. I've been deserted up at the head table. If there are no other questions, I think we can break for lunch and convene again at 1:00 and we're on schedule. Thank you all.

[Luncheon recess.]

A F T E R N O O N S E S S I O N

CHAIRPERSON WACHSMUTH: Is Heather Klinkhamer here? Heather? Carol Tucker Foreman is unable to join us, so we may have a very small panel.

Dr. Potter?

CONSUMER PANEL

DR. POTTER: Let's get back. I hope everyone enjoyed lunch. Our first panel this afternoon is the consumer panel. Darren Mitchell from the Center for Science in the Public Interest is here. Carol Foreman, as Kaye said, is unable to come. We haven't seen Heather, but if she comes in after Darren is done, we'll go into her presentation. Darren?

MR. MITCHELL: Well, it looks like I'm alone up here, so I hope I do a good job, although I did speak with Heather briefly last week and I think we're on the same page, pretty much, on this issue.

Good afternoon. My name is Darren Mitchell. I am staff attorney for the Food Safety Program at the Center for Science in the Public Interest. CSPI is a nonprofit consumer advocacy organization that focuses on nutrition, food safety, and alcohol issues and we're largely supported by our one million members in the U.S. and Canada. Thanks very much for inviting me here to present CSPI's views on

how the food code can best protect consumers from foodborne illness caused by the contamination of ready-to-eat foods by food workers.

The committee has already heard about the enormous number of foodborne illness outbreaks that have been attributed to the transmission of pathogens from workers' hands to food. The white paper developed by FDA attests to the range of foods that can serve as the source of such outbreaks, as well as the diversity of pathogens that can be involved.

As FDA noted and has already been emphasized today, bare-hand contact of foods by infected employees is the culprit in far too many of the 81 outbreaks that we saw in the FDA white paper. Despite the overwhelming epidemiological data demonstrating that hand-to-food transmission of pathogens is a significant cause of foodborne illness, however, there are some who advocate eliminating the prohibition on bare-hand contact with ready-to-eat foods that's contained in the current FDA food code. As I'll explain, the available evidence does not support that potentially disastrous change.

Although I studied biochemistry as a college student and a graduate student, I also went to law school, for better or worse, and as a result, I tend to invoke a

concept of burden of proof when I address issues like the ones we're discussing today. Specifically, I asked myself, who has the burden of proving that an established legal or regulatory requirement should be changed?

When applied to the bare-hand contact issue, the answer, I think, is clear. Both FDA and the voting delegates of the Conference for Food Protection have decided that, in general, consumers' health is protected by prohibiting food preparation employees from handling ready-to-eat foods with their bare hands. Despite having had numerous occasions to do so, neither FDA nor the conference has decided to do away with the bare-hand contact prohibition.

Consequently, those who wish to rescind the ban on bare-hand contact have the burden of proving, with sound scientific evidence, that permitting workers to use their bare hands when they handle ready-to-eat foods would be at least as protective as the use of gloves and other utensils.

CSPI does not believe that the opponents of the current standard have satisfied that heavy burden. As I'll explain, there is no scientific basis for doing away with the bare-hand contact ban. None of the studies cited by opponents of the prohibition calls into question the conclusion that an effective hand washing regimen in

conjunction with the use of gloves or other barriers by food handlers affords the greatest level of protection against the transmission of pathogens from food workers' hands to food, and remember, I am talking about effective hand washing and proper use of gloves.

Provided that workers wash their hands with sufficient frequency and change their gloves whenever necessary, the combination of good hand washing practice and gloves will better prevent pathogen transmission than either hand washing or glove use would alone.

As some have observed, however, things do break down when food workers fail to follow proper sanitary practices while wearing gloves or using other utensils. Some of the speakers we heard this morning argued that prohibiting bare-hand contact actually endangers, rather than protects, the public from the spread of pathogens from workers to food. Gloves, the argument goes, give food handlers a false sense of security and mislead them into believing that hand washing and other hygienic practices are unnecessary. In fact, say the opponents of the bare-hand contact prohibition, because food handlers never get the sensation of having dirty hands, they are less prone to wash their hands or to change their gloves when necessary to

avoid accumulating potentially dangerous levels of contamination.

Well, while all that may be true of many retail establishments, there is no doubt that failure to comply with good hand sanitation practice is a symptom of poor management. Is it really any wonder that poorly trained and inadequately supervised employees revert to unhygienic practices? It is the responsibility of the retail establishment's management to ensure that food handlers are properly trained and supervised, that their compliance with good food safety standards is closely monitored, and that transgressions are swiftly detected and corrected.

Poor management as reflected in food workers' lousy compliance with sanitary standards should not drive public health policy making. Food code standards should not be defined by what under-trained and inadequately supervised workers are capable of achieving. Rather, regulations should be based on those practices that afford the highest degree of safety when they are diligently followed by well-trained, properly supervised workers.

The very best practices in retail food establishments include frequent hand washing combined with the use of gloves or alternative barriers to hand-food

contact. Therefore, CSPI remains a strong advocate of the current bare-hand contact prohibition.

However, to obtain the greatest public health benefit from that prohibition, management of retail food establishments must take every step necessary to ensure that food preparation workers consistently follow good hand sanitation practices. The prohibition obviously will offer little protection if food handlers neglect that basic hygienic standards goes unnoticed or uncorrected.

Managers already have many of the tools that are necessary to monitor their employees' sanitation practices, and I'll give you a very, very simple example. Many State and local restaurant codes require hand washing sinks in the food preparation area where they can be seen by managers. Therefore, those managers can require that workers wash their hands every time they start handling food and they can easily detect when that mandate is not being followed. For that reason, claims by restaurant managers that they cannot supervise their employees' hand sanitation practices ring hollow.

I'd like to propose--and we're not the only group to advocate for such a system--a systematic way for establishments to achieve full compliance with sanitary standards, and that would be to develop and implement

quality assurance programs that include monitoring and enforcement of all hand sanitation standards. We advocate making such programs mandatory in all retail establishments. A crucial component of such programs are ongoing training, and I am saying ongoing training, and education of food workers, and this committee, as well as the Federal Government, can facilitate the development of such programs by identifying and funding research projects that will lead to the creation of improved training courses and materials and will help identify the most effective means to monitor and to enforce good sanitation practices in retail establishments.

I'd like to spend a couple of minutes outlining our vision of what an effective quality assurance program would look like. First and most fundamentally, an effective control program would require that workers follow a prescribed hand washing regimen. Proper employee hand washing assures a basic level of sanitation that must be achieved in all establishments, no matter what. Neither CSPI nor anyone else who cares about safeguarding public health would ever assert that the use of gloves or other barriers is a replacement for good hand washing practice.

To help food workers follow good sanitary practices, an effective plan would specifically describe

what constitutes a good hand washing regimen in terms of duration, water temperature, soap and sanitizer use, and other things. It would also specify the required frequency of hand washing and spell out exactly when hand washing must take place. Although there remain some controversial issues, much of the research that was summarized in FDA's thorough white paper provides a basis for defining a proper hand washing regimen. That information, we believe, should be incorporated into the food code, where it can serve as a model for adoption by retail establishments when they craft their quality assurance programs.

In addition, a protocol for testing the efficacy of hand washing soaps and hand sanitizers should be developed an incorporated into the food code. Retail establishments should be required to use only soaps and hand sanitizers that achieve stringent performance standards under such a protocol.

An effective quality assurance plan would also require the proper use of gloves and other barriers to hand-food contact. The use of utensils other than gloves, such as tongs, spatulas, ladles--we have heard some of that this morning--that obviate the need for direct hand contact should be mandated wherever they can be used feasibly.

Overall, the quality assurance plan should aim to minimize hand-food contact wherever possible. If gloves are required in the preparation of foods, the plan should spell out how often gloves must be changed and what activities would trigger the need to change gloves. The plan should also mandate that employees follow a proper hand washing regimen, both before donning and after removing gloves.

We also encourage the development of a testing protocol for gloves and its incorporation into the food code, as well, so that establishments can be required to use only those gloves that, again, satisfy stringent performance standards relating to durability, permeability to microorganisms, tightness of fit, et cetera. This committee can aid in the development of such a testing protocol.

Of course, there are other elements of an effective quality assurance program, and I'll just talk about a couple of them. The quality assurance plan should set forth requirements for the frequent and thorough cleaning and sanitation of counter and tabletops, faucets, utensil handles, other surfaces that can spread pathogens from workers' hands to food. Sampling and microbial testing of such surfaces could provide a means of gauging the effectiveness of the sanitation measures and would also help establishments monitor compliance with sanitation.

In addition, the plan should spell out specific task assignments for all food workers to help ensure that those who handle ready-to-eat foods are not also responsible for tasks that bring them into close contact with customers, money, cleaning equipment, and other potential sources of pathogenic contamination.

Also, as has been discussed at length this morning, the plan should include means to ensure that sick employees have incentives not to report to work when they're ill and to go home when they are found to be ill during the work day.

The many components of a quality assurance plan that I've just outlined will yield little in the way of improved safety if the overall program does not also include effective monitoring and enforcement measures and if it is not managed by qualified personnel. I cannot overemphasize the importance of good management in ensuring that food workers, including the least experienced and the most unmotivated food workers, comply with all good sanitary practices. A mandatory certification program, at least for food service managers, should be required everywhere.

Now, a further word about glove use. Please understand that CSPI does not have a glove fetish. We do not support the bare-hand contact prohibition because we

want to complicate the lives of food managers and employees of retail establishments. Rather, we believe that avoiding bare-hand contact provides an important safeguard against the transmission of pathogens from food handlers' hands to food.

But we agree that more research under the actual conditions present in food service settings should be undertaken to determine whether hand washing, combined with proper glove use, is truly the best way to protect consumers. If such studies establish that allowing bare-hand contact will actually prevent more foodborne illness than the use of gloves or other barriers in some instances, then we would, of course, support amending the current food code requirement. We certainly don't advocate a requirement that actually jeopardizes public health.

However, we are not at that point now. The only study that we have seen to indicate that washed and sanitized bare hands may, under certain circumstances, offer better protecting than hand washing and glove use is the 1998 study by Findler and colleagues. It's part of the FDA docket, in case anyone's unfamiliar with this research. The study measured the levels of E. coli contamination on workers' hands and gloves after they kneaded contaminated ground beef for three hours under different gloving and

bare-hand configurations. The researchers found that hourly hand washing and sanitization resulted in substantially lower microbial levels on hands when compared to glove surfaces of those who changed their gloves also on an hourly basis.

That study is an important one and indicates that, under certain circumstances, a proper hand washing regimen may confer greater protection against cross-contamination than does the use of gloves, even with regular glove changes and hand washing. However, it is very important to recognize the limited relevance of that study to the question at hand, in our view.

Specifically, the major problem that the bare-hand contact prohibition addresses is not cross-contamination, but rather the transmission of pathogens from infected employees to foods. The reason why is clear when you examine the data in FDA's white paper. Those data show that the vast majority of outbreaks were caused by the handling of food by sick employees.

Although cross-contamination is a very real concern, it can be prevented if management strictly enforces requirements that workers wash their hands and change their gloves after handling raw foods, that food contact surfaces

are thoroughly cleaned and sanitized after exposure to such foods, and that other sanitary measures are employed.

Nonetheless, we do believe that additional studies comparing the effectiveness of hand washing and sanitation versus hand washing, sanitization, and glove use should be undertaken. If such research is carefully designed to simulate the actual conditions present in food service establishments, it will yield important insights into the efficacy of the current bare-hand contact prohibition. This committee should help FDA and industry to design and to initiate such research.

I'd like to shift my focus briefly to the exception that we've heard about this morning to the bare-hand contact ban which is found in the 1999 food code. That exception authorizes State and local regulatory officials to permit bare-hand contact if an establishment institutes a HACCP-based plan that includes control measures to prevent the transmission of pathogens from employees to ready-to-eat foods. CSPI is very concerned that the exception threatens to swallow the whole.

To prevent that from happening, State and local regulators must be diligent in assessing food establishments' HACCP plans and in taking swift and decisive enforcement action against those establishments that permit

employees to use their bare hands without having put in place a truly effective HACCP plan. An exemption should be granted only if sound scientific studies incontrovertibly demonstrate that permitting bare-hand contact under the specific circumstances does not pose a greater risk of transmitting pathogens from employees to food than does the avoidance of bare-hand contact.

In addition, to be eligible for the exemption, the food establishment should implement a HACCP plan that includes all of the components identified in Annex 3 to the 1999 food code and the State and local regulatory authorities should take steps to verify on a routine basis that food establishments' HACCP plans are effective in preventing the contamination of ready-to-eat foods.

I see my time is running down.

DR. POTTER: Yes.

MR. MITCHELL: I'll conclude. In conclusion, those who advocate eliminating the current bare-hand contact ban have not satisfied their scientific burden. The prohibition should not be modified or rescinded based on observations or data relating to worker noncompliance with good hand sanitation practices which merely demonstrate that the management of retail food establishments have failed to adequately train and supervise their employees.

Most importantly, we think, management must rigorously enforce food safety standards and be tough on employees who don't follow the rules. Retail establishments whose employees continually neglect good sanitary practices should be closed. As we all know, consumers are eating more and more of their meals away from home and, therefore, rely to an ever-greater extent on food establishments to handle their food safely.

This committee should use its substantial expertise to identify research activities that will promote the development of training and education programs capable of reaching even the most unmotivated employees. In addition, the committee should help FDA and the CFP to develop monitoring and enforcement strategies that will help management maximize food workers' use of the very best practices. Given the tremendous number of consumers who are affected on a daily basis by practices in retail establishments, you face a tremendously important task. Thank you for your time.

DR. POTTER: Thanks. Heather, are you ready?

MS. KLINKHAMER: Will someone give me a signal when I have five minutes left and when I have one minute left? It's 15 minutes altogether still, right?

DR. POTTER: Right, 15 altogether. We'll signal at the end of ten.

MS. KLINKHAMER: Thank you. I am Heather Klinkhamer, Advisory Board member of STOP, Safe Tables Our Priority. STOP was formed in the summer of 1993 by victims of foodborne illness. Most of its founders were parents of children maimed or killed by E. coli 0157-H7 in meat. STOP provides victim support, educates consumers about foodborne illnesses and food safety, and advocates to improve food safety policies. STOP's purpose is to reduce illnesses and deaths caused by foodborne illness. I am delighted to be here today to present STOP's position on bare-hand contact with ready-to-eat foods.

STOP participated in the 1998 Conference for Food Protection, which made the recommendation that the committee examine this issue. The other two consumer representatives at the conference, the Center for Science in the Public Interest and National Consumers League, joined STOP in opposing the resolution to alter the food code to allow bare-hand contact with ready-to-eat foods.

I want to talk a little bit about putting risks and hazards into perspective. All segments of the food business--farmers, ranchers, producers, retailers, and regulators--communicate that food safety is their primary

goal, and it is important that this goal remain at the apex of our collective concern. Unfortunately, the goal is often diminished by lesser concerns, such as profit and convenience.

Incidents in which bare-hand contact with food has led to hundreds and thousands of foodborne illnesses are well documented. It is difficult to reconcile efforts to weaken the food code's bare-hand contact ban with efforts to improve food safety. In at least two food worker contamination outbreaks identified in FDA's white paper, hundreds and thousands of people could have avoided illness if food workers had used spoons rather than their bare hands to mix food.

Every year, thousands of Americans are forever changed as pathogens such as listeria or E. coli 0157 touch their lives. Foodborne illness victims always place consumer health and safety above all other food policy considerations. They work hard to keep other food safety stakeholders focused on health and safety goals by reminding everyone that the pathogens we address elicit a real and profound toll.

Today, I'm going to relay the experiences of some of STOP's members in an effort to reacquaint all present with the consequences of foodborne illness.

The picture at the bottom is a photograph of Alex Donnelly [ph.]. In 1993, Nancy and Tom Donnelly lost Alex, who was six years old. He died four days after onset of E. coli 0157-H7 illness symptoms. The pathogen was so destructive that they were not able to donate his organs to help other children live. For example, the bacteria's toxins liquified portions of Alex's brain. More recently, in the New York State Fair outbreak, a child died who also had a brain liquified by the toxin.

The top picture is of Haley and Chelsea Bernstein. The Bernsteins thought that they were eating a healthy meal when they served organically-grown lettuce to their family in 1996. Unfortunately, the lettuce was contaminated with E. coli 0157 and both three-year-old Haley and seven-year-old Chelsea contracted illness that required hospitalization. Haley's illness developed into HUS, hemolytic uremic syndrome. Her treatment included several surgeries, including brain surgery. She was hospitalized for four weeks and is now partially blind.

This is a photograph of Damien Hersink [ph.], who contacted E. coli 0157 at a Boy Scout camping trip. He developed HUS, which kept his hospitalized for seven weeks. He had seven surgical procedures in the five weeks that he was in pediatric intensive care. His kidneys failed. The

lining of his heart was removed and his intestines were punctured. He was on dialysis and a respirator for three weeks. After the illness, he suffered from severe malnutrition. He lost 20 percent of his body weight. He had to learn how to stand, sit, and eat again. Damien has been hospitalized three times this year with small bowel obstructions due to abdominal scarring, and it's about ten years since his bout with E. coli 0157, so you can see how the repercussions of his illness are quite far-reaching.

This is--I don't know if you can see this well, but this is a photograph that shows the incision, which goes from his collarbone down to his belly button.

By the way, the next series are quite graphic. This is Brianne Kiner [ph.], who was one of many children hospitalized after eating contaminated ground beef in the Jack-in-the-Box outbreak of 1993. She spent two months in intensive care and nearly six weeks in a coma. Her hospitalization lasted nearly six months. She suffered from thousands of seizures and three strokes. Again, every organ in her body failed. After she was released, she required acute care to learn how to walk and to talk. Next slide.

This is an incision that had to be made because the organs of her body had swelled so much that her skin was going to rip, and so they thought it better to make an

incision. She is now diabetic and will require additional surgery to repair her damaged intestines. Due to her illness, Brianne will never be able to bear children.

I had other examples, but I'm just going to continue on for the sake of time.

STOP's perspective is that of people who have suffered profoundly from gaps in the nation's food safety net. Many here today have heard the CDC's recently released estimates of 76 million illnesses and 5,000 deaths attributed to foodborne illnesses each year in the United States. When one ponders the faces and the lives behind each number, the gravity of our responsibility to forge responsible food safety policies is more apparent. America's most vulnerable population is suffering the brunt of foodborne illness.

Nineteen-ninety-seven FoodNet data revealed that the rates of illnesses for infants and children are double, triple, and quadruple the rates of cases for all other age groups combined. In one example, children under one year of age contracted Salmonella at a rate of 111 illnesses per 100,000, which is four times the rate of the next-highest age category, which happens to be children between the ages of one and ten years of age.

Infants and children are suffering from Salmonella and Shigella twice as often as all other age groups combined. Their rate of Yersinia infection is 13 times the rate for all other age groups combined.

The fact that our nation's children are suffering from a disproportionately high foodborne illness rate is terrible. We know this is a susceptible population and, therefore, the risk of severe illness and death is higher. What compounds the tragedy of this situation is the fact that many of the infants and children who survive these illnesses will inherit a lifetime of severe health complications that will forever hamper their lives.

The loss of potential in those at the start of life is a terrible shame. It is also very costly. Providing health care to a population acquiring acute need of care at an early age is expensive because health care expenditures will be made for a greater length of time. USDA's Economic Research Service estimates that the top seven foodborne pathogens cost the U.S. between $5.6 and $9.4 billion annually in lost productivity and medical expenses.

Foodborne illnesses are more than belly aches. STOP's victim members have suffered brain damage, stroke, heart attacks, kidney failure, liver failure, and blindness

due to foodborne illness. Our members have spent between $300,000 and $500,000 to treat single cases of HUS induced by E. coli 0157 infection. These actual expenditures far exceed the Economic Research Service's estimates of HUS treatment costs.

One in five Americans lacks health insurance. This is a significant proportion of our population, approximately 43.4 million people. The public tends to hear about foodborne illness incidents in which victims are compensated for medical expenses and pain and suffering, yet it is more often the case that no entity can be held responsible for covering the exorbitant medical expenses. STOP's membership includes those who not only suffer from the lifelong medical complications but those who also suffer extreme economic hardship resulting from foodborne illness and its repercussions.

Even those with health insurance have great cause to worry. If they ever lose coverage for their child through a loss of employment or a missed insurance payment, that child may never get insurance coverage again. This reduces the options of those who survive these illnesses.

The ramifications of these illnesses go on and on. The costs are often not quantifiable. It is impossible to estimate the toll of the many restraints imposed on lives,

of the subsequent marital strains and ruptures, or of the grief and suffering borne by children, parents, and communities. Each time those present hear a foodborne illness statistic, I encourage you to think about the people behind the numbers and the impact of the illnesses on their lives and on their futures.

How much time do I have? I did have a section here about epidemiological data, but I think I presented enough on risks and hazards.

I'm going to now talk about some of the factors in the retail community that--the roles, the attitudes, and the enforcement that we perceive as relevant to this issue. I'm focusing on retail because at the retail level, there's a great number of people who are fed at one time, as opposed to home situations, and the outbreaks that were picked up by FDA in their literature review were overwhelmingly linked to retail establishments.

There's wide agreement that frequent hand washing and lack of bare-hand contact are beneficial for food safety. Consumers frequently call the STOP hotline to complain about poor hand washing facilities at restaurants and food workers touching food with bare hands.

In a 1998 consumer study, 77 percent of participants agreed that an unsanitary restroom would

strongly influence their opinion of an eating establishment's food handling practices. Forty percent of respondents agreed that a well-stocked food worker hand washing station would positively influence their opinion of an eating establishment.

It is widely recognized through the industry policies and government regulations that retail establishments have a responsibility to prevent foodborne illness by getting food workers to wash hands and to avoid bare-hand contact with food. But violations of these policies occur too often.

A New York newspaper's review of three county grocery store inspection records found that inadequate employee hand washing facilities accounted for 20 percent of store violations. Because 139 stores in this catchment area only passed inspection on average 58 percent of the time, 20 percent is a significant number of hand washing violations.

A Philadelphia news article about hot dog safety recently noted that food worker staffing in a major sports stadium relied on the same dirty soapless bathrooms used by the fans.

Many of us here today probably have visited restaurant bathrooms that posted signs informing food

preparers that they must wash hands, but the facility lacked soap, hand dryers, towels, or warm or hot water.

Some members of the retail industry blame high worker turnover for hand washing inspection violations. In a series of Michigan grocery store inspection articles by the Detroit Free Press, a store manager and a trade association representative said difficulties attracting and maintaining employees diminished food safety education efforts and sanitation performances. However, there is evidence that a significant number of retailers simply do not appreciate the important role hand washing plays in preventing transmission of pathogens from food workers to customers.

Food service industry consultant Archie Taylor told 1998 Public Voice annual conference participants that hand washing is the food safety procedure most often overlooked. She said, food workers are educated and know they should wash their hands, but hand washing doesn't take place because workers are busy and management doesn't insist that hand washing procedures are followed.

A posting on USDA's Food Safe list serve corroborates this assertion. A Serve Safe instructor complained that restaurants are more interested in acquiring

food safety training credentialed staff than implementing the food safety practices the staff learned.

Clearly, food safety training and food safety policy implementation are important components of industry efforts to comply with regulations and reduce public health risks. An article in an Australian food industry journal noted, "A successful hygiene program requires a committed manager. If management is not concerned about hand washing, employees will not be concerned. Recognition should be given to employees who adhere to personal hygiene principles."

The New York newspaper article recently regarding violations of food safety retail regulations cited experts who correlate adherence with food safety practices to management leadership. "Stores that regularly pass inspection make it clear to employees that food safety is important."

I have no time? Okay. I'll very quickly wrap up. I'm just going to mention a couple of the recommendations that STOP has.

We support establishment of food safety standards that protect public health. Protection of the most vulnerable consumers should be the goal of the minimum standard. A lack of scientific data on fine details of

regulation should not become an excuse to remove public health protection established in response to actual and repeated incidences of foodborne illness.

I'm just going to close right there. Thank you very much.

DR. POTTER: Questions from the committee for Heather or Darren?

[No response.]

DR. POTTER: Okay. Thank you very much.

INTERVENTIONS

DR. POTTER: We'll go into our next panel, then. The first presenter will be Jack Guzewich from FDA.

MR. GUZEWICH: One of the advantages of being in town is that when you see you have a problem, you can adapt quickly, and after the problems with the Powerpoint this morning, I've gone to the more low-tech overhead transparencies for my presentation today rather than the Powerpoint that I had planned on using. I want to thank Carol for helping out on this.

I want to make special attention to Dr. Marianne Ross, who is not with us today because she is overdue to have her first baby. She did the bulk of the work on both of our white papers, and I would much rather have her up here getting the credit for doing this. Unfortunately, that

is not going to be the case today. Go to the next slide, please, Carol.

Food worker contamination can either be from sources in the bathroom acquired or in kitchen acquired. This distinction is not always made in the discussions you hear on this issue, but it's important to keep those distinctions in mind.

In public health, we use the multiple barrier approach on many of the problems that we encounter. In multiple barriers, you try to identify the links in the chain of infection and then implement interventions at as many links as possible to break the chain and prevent future infections.

The review I'm about to present will address the removal and barrier interventions that can be used to minimize or eliminate the contamination of ready-to-eat foods by food workers. Next slide, please.

The information that we are presenting here was identified in an electronic literature search from submissions and response to a Federal Register notice, information already in FDA files, and unsolicited information that was provided. Most studies were done in a health care setting, where cross-contamination and skin organisms are a bigger concern than are interifetiologies

[ph.]. No judgments have been made concerning the merits or the methods used by the authors. This is a presentation of the body of information available to form decisions and opinions at this time. Next slide, please.

There are a couple of terms you may have heard already today that you're going to hear more of as discussion continues. One of them is transient and resident microflora. Resident microflora normally reside on the skin. They're not easily removed by mechanical friction. They are generally not pathogenic in terms of food safety, the exception to that being Staph aureus. They reside in the layers of the skin and the sebaceous glands. Next slide, please.

Transient bacteria, on the other hand, do not normally reside on the skin. They are considered skin contaminants that are acquired from environmental sources. They can be pathogenic. They are loosely attached to the skin surface and they can easily contaminate food products if hands are not washed adequately.

We will now move on to some of the information in the studies. Next slide, please. First, we'll talk about contamination of hands. The transfer of microorganisms and viruses occurs less frequently when contaminated material or hands are dry. Some bacteria and viruses survive on hands

for several hours. Listeria monocytogenes was shown in one study to survive for over 11 hours on fingertips. Hepatitis A was shown to survive for seven hours in a similar situation.

But we have shown in our epidemiologic paper that hand contact with garnishes has led to outbreaks of Hepatitis A and Shigella species. Specifically, a bartender with Hepatitis A prepared drinks and just placed the garnish on the drinks and that was the source of cross-contamination for the garnish. In another outbreak of Shigella, an employee sprinkled parsley on a carrot dish and that was the level of contamination necessary to spread the Shigella bacteria. Next slide, please.

The amount of viruses, particularly rotavirus, transferred is related to the amount of pressure applied during contact, the length of time of contact, and the degree of dryness of the inoculant. Rotavirus after drying on the hands for 20 to 60 minutes can be transferred with a pressure of one kilogram per centimeter squared for ten seconds. Most transfer studies were conducted using viruses rather than bacteria, which is kind of interesting in our review, and that one kilogram per centimeter squared, that number relates about to the pressure it would take you to

pick something up. That's about the level of pressure that relates to. Next slide, please.

In bacterial transfer, surfaces contaminated with low numbers of bacteria can contaminate fingers. In one study, 120 organisms per centimeter squared of E. coli, Salmonella, and Staphylococcus on the surface were readily transmitted to the fingertips.

Parasites is another issue. There really wasn't much in the issue about parasites. The only thing we could see in the literature was that ova are more resistant to the cleaning compound but can easily be removed by mechanical action of hand washing, but there really wasn't much else we could say about it. Next slide, please.

Hand washing in health care is the removal of soil and transient microorganisms from the hands. Detergent-based cleaners are plain, non-antimicrobial, non-antiseptic soaps that have no bacteriocidal activity and are used primarily for the physical removal of dirt. On the other hand, hygienic disinfection is also known as the health care personnel hand wash and it includes some type of antimicrobial agent along with a detergent. A discussion of the various hand wash factors will follow. Next slide, please.

Hand washing technique. In the papers we were able to see, the quantity of soap used in washing hands varied from a range of three to five milliliters when an antiseptic soap was being used to about one milliliter for non-antiseptic soaps. The duration of washing ranged from five to 30 seconds. Important here is the idea that you have to have mechanical action. A lot of the removal of the organisms is happening during the mechanical action and the action of the detergent that's involved there.

The numbers of organisms decrease as frequency of hand washing increases, but only to a certain point. High-frequency washing, which was defined as greater than 25 times per day in the health care setting, shows increased skin irritation, increased bacterial counts, which can be due to defatting of skin, altering pH, removing skin lipids, changing normal microflora, or decreasing moisture. Dry skin causes increased shedding of skin cells and microflora. Next slide, please.

Mean bacterial counts for unwashed hands in one study were significantly greater than for hands washed for ten seconds. Washing for ten seconds removes transient bacteria--remember, those are the ones on the surface--from hands, resulting in decreased numbers of recovered organisms from the hands. Mean data for hands washed for three

minutes were not significantly different from unwashed hands or for hands washed for ten seconds. Washing for three minutes reduces transient bacteria, but also brings resident microflora in the deeper layers of the skin to the surface, thus increasing the total number of organisms recovered from hands. Next slide, please.

Friction, as I said a minute ago, rubbing hands together or using a scrub brush, allows for greater reduction of transient bacteria, even with plain soaps or detergents. Transient bacteria are more easily removed than the resident bacteria. Friction is key to removal of these bacteria. A temperature of 110 to 120 degrees Fahrenheit at water flow of two gallons per minutes was suggested for hand washing most often, and water temperature should be comfortable for the user was also frequently cited. Next slide, please.

Currently, there is no uniform approval method for evaluation of hand wash products, and the next couple of speakers are going to talk more about that. One thing that's been proposed by the soap and detergent industry is called the Health Care Continuum Model. This addresses the need for uniform evaluation and testing methods. Products used for health care are chemically and antimicrobially similar to those used in food service. However, those used

in food service should also remove the organic load of food ingredients and fat. Next slide, please.

Plain soaps and detergents are used for their mechanical removal of transient organisms. Antimicrobial agents are used for mechanical removal when they're combined with soap, and killing or inhibition of both resident and transient organisms. Next slide, please.

I'm just listing here the antimicrobial agents. One of the next speakers is going to talk about them in a little more detail. But typical antimicrobial agents, either incorporated in hand washes or in hand sanitizing compounds, include alcohols, chlorhexidine gluconate, triclosan, iodophors, and PCMX. PCMX is perachlorometaxylenol [ph.], for you chemists in the group. Antimicrobial agents can be used as an ingredient in a hand wash or as a separate hand sanitizing gel, as I just said. Next slide, please.

Hand drying methods. There were a few, but only a few, studies on the use of hand dryers. One study found an increase in the numbers of bacteria on hands after hot air drying. A contradictory study found that, irrespective of the hand washing agent used, electric air drying produced the highest reduction in numbers of E. coli and rotavirus on hands when compared with paper or cloth towels. Next slide, please.

In one study, paper towels accounted for a 29 percent reduction in mean value of the bacteria from hands after drying with paper towels, a 95 percent reduction in numbers of S. aureus after rinsing with tap water alone and drying hands with paper towels, and when friction was applied when drying, that further reduced the bacterial counts. Now, paper towels can be useful, also, in handling faucet and door handles with clean hands, and it has been pointed out that hand contamination can occur from touching the paper towel dispenser exit, cranks, buttons, and levers.

Cloth towels in this study showed a 26 percent reduction in bacterial counts on hands when dried with a continuous cloth towel. The bacteriologic quality of cloth towels was found to be inferior to that of the paper towels, either due to the laundering process or due to the fact that bacteria can be transferred from one user to the next. Next slide, please.

A major advantage to hand washing machines is the consistency of hand wash produced and the monitoring capability of use of the machines. In one study with plain soap combined with 0.3 percent triclosan manual wash compared to chlorhexidine gluconate machine was, it was shown that baseline measurements of the manual wash had a 0.7 log level of organisms, whereas automated wash had a 1.2

log reduction in organisms. That's the number of organisms reduced. The variability among wash results was also less for the machine wash. The manual wash had a 0.7 log variability, whereas the automated wash had a 0.5 log variability in results. Next slide, please.

Barriers. Barriers have been spoken of somewhat already today. There are three kind of categories, if you will, of barriers. There's gloves, utensils--the tongs, spatulas, et cetera, scoops--and then deli wraps or napkins. We were only about to find published information on the use of gloves. None was available on the other barriers, and most of the glove research has been done in the health care setting rather than in the food service setting. Next slide, please.

Most of the studies that were done are cataloging problems with gloves and in some way detailing those problems, but they also seem to conclude there is some value in their use. In this study I'm showing here now, up to 18,000 Staphylococci organisms can pass through a single glove hole during a 20-minute period, despite the fact that hands were washed prior to donning. Bacteria and viruses can both leak through the gloves, and organisms on hands can multiply rapidly inside the moist environment of the gloves.

In this hospital study, 63 percent of vinyl gloves leaked, compared to seven percent of latex gloves. In the same study, 43 percent of unused vinyl gloves had perforations. This study was at high-use levels in a health care setting, which included attaching cap needles to syringes, removing needles several times, wrapping or taping blunt objects. Next slide, please.

Latex has been found--this is latex on the surface of the outside of the glove, now, not on the inside--latex has been found to trap microorganisms that are not easily removed with friction or cleansers. This was in a study where they were trying to see if you could wash and reuse gloves. After washing with several commercial products, recovery of Staph aureus was minimal, with low levels being shown there. Hand washing is recommended immediately prior to gloving and after glove removal. Hand washing after glove removal removes the bacteria that have built up during the time when the glove was being worn. Next slide, please.

In summary, this section described highlights of the removal of pathogens and one barrier to bare-hand contact with food. Removal of pathogens can be accomplished by a combination of various hand washing techniques, hand wash agents, hand drying methods, and sanitizing gels or wipes. Next slide, please.

Barriers to bare-hand contact include gloves, deli wrap, and utensils. Glove material, duration of wearing, and hand washing prior to and after wearing are important considerations that will determine the effectiveness of glove use. Next slide, please.

There are three interventions that can be used to minimize or eliminate contamination of ready-to-eat foods by food workers: Removal of food workers from activities such as food preparation, removal of pathogens from hands of food workers, and barriers to bare-hand contact. Thank you.

DR. POTTER: Thanks, Jack.

The next presentation is Debbie Lumpkins from FDA.

MS. LUMPKINS: Well, after much consideration, I decided to take the steps, so let's see if we can get this working.

[Pause.]

MS. LUMPKINS: After a lot of waiting, I hope what I have to say is of some value. Good afternoon, ladies and gentlemen. My name is Debbie Lumpkins. I'm a microbiologist with the Division of OTC Drug Products. I've been asked to tell you a little bit about the regulation of hand washing products.

So today, I'm going to be covering a number of issues. One of them is the categories of hand washing

products that are available, the regulatory history and schemes for these products, the highlights of the agency's proposal for health care and accepted drug products, comments on the proposed rule, and a public meeting that was held just last year on the issue of food handler hand wash testing.

Basically, hand wash products can be broken down into four simple categories. One of them, as Jack mentions, is the non-antimicrobial soaps. These are products that don't contain an antimicrobial ingredient. They're basically surfactants.

The next group are consumer hand wash products. Those are those intended for use in the home. Health care personnel hand wash are the ones for use by health care professionals--surgeons, nurses. Food handler hand wash is a new category for OTC drugs to be dealing with. They're the products intended for use in food processing plants.

Based on the fact that three of these categories contain active ingredients to help prevent disease, they're considered drugs under the act, and on display now is sort of our thumbnail sketch of what constitutes a drug under the FD&C Act. The agency emphasized this point by its policy statement in its first aid antiseptic rulemaking, in which

it stated that any claim, such as antimicrobial or kills germs, is a drug claim.

However, some antimicrobial-containing products intended for use by individuals involved in food processing have been regulated outside of this scenario. USDA regulations formerly required that the use of hand cleansers and sanitizers that it certified for use in meat and poultry processing plants. The basis for this certification was the ability to demonstrate an equivalency of 50 parts per million chlorine and inclusion of the ingredient on the agency's safe indirect food additives list.

Now, consumer and health care professional hand washes are regulated by two separate pathways. The first of these is the new drug approval process. This is a product-specific approval process that is based on proprietary information and data submitted by the sponsor of the MDA for the individual product.

An alternate process is the one that's been ongoing for quite some time. It's the OTC drug review. Basically, it is an evaluation of active ingredients by drug product category, so there's no product-specific approval. To be included in this review, products need to be able to demonstrate that they've been marketed prior to 1975.

The OTC drug review is a public rulemaking. It involves notice and comment and it's a three-stage process. Basically, the first stage is an evaluation of the available data on a particular category by one of our advisory committees. The advisory committee makes its recommendations and FDA publishes these recommendations in the Federal Register. Interested parties are given a chance to submit their comments and any additional data and information that we have, and then based on that, the agency develops a proposal in which we have evaluated the comments and looked at the available data and this is what would be the proposed monograph.

I guess now would be a good time to tell you about what goes into an OTC drug monograph. The OTC drug monograph allows manufacturers that are in compliance with that monograph to market a product without prior approval. The monograph specifically identifies active ingredients, their safe and effective concentration, and what the appropriate labeling should be. In some cases, they also propose final formulation testing.

Specifically, our proposed rule that dealt with hand washing products is the health care antiseptic proposed rule that was published in June of 1993--1994. That slide's got a typo on it. Basically, this proposal covers

professional and consumer use hand washes. It proposes an evaluation of the food handler hand washes, but it doesn't include any proposals. In that proposal, we solicited data and requests for comment on what should be appropriate in the labeling and in the testing and in the way of active ingredients for these products.

Now, the health care antiseptic TFM is a little bit different from most of our OTC monographs in that it does propose final formulation testing. Manufacturers are expected to conduct these tests and keep these data on file. It's a two-tiered test for the health care hand wash products. The first tier is an in vitro demonstration against an array of organisms that are frequently associated with nosocomial infection. They're also required to do a time kill study against representative organisms.

The requirements for this are pretty specific. There's a list of about 25 organisms. For the minimal inhibitory concentration, the manufacturer would be required to test 25 American-type culture strains and 25 fresh kill isolates of each organism listed. Beyond that, for the time kill studies, all they need to do is the representative organisms that are on that list and they're to use the ATCC strains only.

For the in vivo demonstration of hand washing products, it's a hand wash protocol that uses a microorganism. It's the test for the removal of transient organisms. Basically, the health care professional hand washes and the consumer use products are expected to meet the same criteria. The criteria are, first, they must demonstrate a two-log reduction within five minutes of the first wash. They must, beyond that, demonstrate a three-log reduction after the tenth wash.

Now, there's another group of hand wash products that I put in here for completeness, for the surgical hand scrubs. Basically, they do the same in vitro studies, the same time kill studies, but they have a slightly different in vivo hand wash test and different effectiveness criteria. Basically, the effectiveness criteria are pretty substantial, a one-log reduction on each hand within one minute after the first scrub, and it must not substantially exceed baseline for six hours. Beyond that, a two-log reduction at the end of the second day of the testing, and a three-log reduction at the end of the fifth.

All of the hand wash products included in this proposal are also required to demonstrate that their active ingredients have not fostered any resistance, and basically, manufacturers are given an option to pick either using in

vitro testing, which involves the serial passage of the organism through increasing concentrations of the active ingredient, or do a literature search.

As I noted before, the proposed rule allowed people the opportunity to comment. We got many, many comments. Most of those comments were on the testing. But the most significant of the comments--I'm not trying to minimize any of the others, but one of the biggest issues that FDA has to deal with at this point is comments that noted the limited scope. Remember, I said the proposed rule only covers professional use products and one consumer hand wash, those for in the home. The Health Care Continuum Model is broader. It's like a monograph in and of itself. It has effectiveness criteria. It covers professional hand use products. It can cover food handler hand washes and body washes. It's very broad. The agency is still evaluating that and has had more than a few meetings on how we feel about this model.

I guess the most current development is a technical meeting that was held in July of last year, where we discussed how do we incorporate the food handler hand wash testing into the testing scheme that's proposed in the monograph. A number of the issues that were raised were things that have been talked about here today over and over

again--effectiveness against viruses, effectiveness against fungi, effectiveness against protozoa. We also discussed what desirable attributes for these products should be, and basically, you're as up to date as I am on the subject. Thank you.

DR. POTTER: Thanks, Debbie.

The next presentation--again, we will have questions for all of the speakers at the end of the session. The next presentation is Michael Dolan.

MR. DOLAN: Good afternoon. I had a speech teacher in high school whose name was Mr. Flynn. He and I didn't get along real well, but he did have some occasional advice for me. He said, Dolan, you'll be a passable speaker if you remember a few basic rules. Number one, don't speak after lunch. Number two, don't follow an animal act or comedian. And the last rule and most important, never, ever speak in a room where you have two opposing sides of a hot issue. So two out of three ain't bad.

I'm Mike Dolan. I'm the Vice President of R&D for GOJO Industries. We are a developer and marketer of professional skin care products, ranging from non-drugs to drugs, the whole gamut that will be discussed. I've got about ten years' experience in antimicrobial skin care products.

However, today, I'm not representing my company. I'm speaking on behalf of the Soap and Detergent Association and the Cosmetic, Toiletry, and Fragrance Association. We have a coalition who has been working for five-and-a-half years now in response to the monograph and proposing various approaches to regulation of skin care antiseptic products. Our membership represents a vast majority, probably 95-plus percent, of the producers of domestic detergents and skin care products, including the products that are used in a food handling setting. Hopefully, we're somewhat in the middle. We're not pro- or anti-gloving at this point, but we do make a living selling hand wash products.

I'm always interested in history. At the risk of starting a war with Dale Morse on who can have the most quotes--some of you have seen this before and you know my penchant--we're talking about regulation and food today, so Benjamin Franklin, one of my favorites, two things people should not ever watch being made are laws and sausages. Of course, Otto von Bismarck, men are better off not knowing how politics and sausages are made.

Congressman Dennis Kucinich, an Ohio native, in addition to having the town of Norwalk, Ohio, which you heard Norwalk mentioned--that's where it came from, the original cases--we also have Dennis Kucinich, the mayor of

Cleveland when it went bankrupt. He also said, a fundamental principle of democracy is that one should never ask how a law or kielbasa is made. This was at a kielbasa and polka festival. Dennis, by the way, is a vegetarian.

And finally, Jack Guzewich, it's not a gloving law, it's a no bare-hands contact law. With all due respect, Jack, 1997, 1998, and 1999.

[Laughter.]

MR. DOLAN: The position I'm going to talk about today--and this is a serious issue. I'm just trying to lighten up a little in the afternoon. Our basic position as a coalition is that hand hygiene is a critical consideration in transmission of foodborne illness. I think we have seen that today. Appropriate hygiene products and regimens can really help reduce the spread of foodborne illness. Situational factors should determine the practices and the product requirements. There is no universal answer for the issues we're dealing with. And finally, a few points on the FDA white paper we think deserve additional comment.

What I'm going to do in the next few minutes is try and add value to the discussions that have already been had. We're starting to see a repeat of certain themes. I'll amplify where I think they're thematic. I'll skip

through some stuff that I had prepared that will be duplicate, try and keep you all on track.

I'm basically going to talk about a definition quickly, some models of hand transmission. We like to work in pictures and mental models that helps us all get on the same page. I'll talk a little bit about hand hygiene products, expand on some of the discussion that's taken place so far, talk about their attributes and summarize their efficacy, and finish with a few conclusions and comments.

Hand hygiene, and I'd like to switch the discussion from hand washing to hand hygiene at this point. It's really talking about the practices associated with cleaning, disinfection, antiseptic, however you want to determine it. The Germans are different from the French, who are different from the Americans. We're all talking about disinfection of the skin to some level. And care of the hands, which no one has talked about, but the actual skin condition of employees is an important piece of this puzzle in a food context setting. We include washing, drying, disinfecting, sanitizing, moisturizing, and gloving. These are all elements of a hand hygiene program.

The primary purpose of hand hygiene in the food setting would be to interrupt the chain of transmission of

microorganisms. This was a model we used in one of the discussions with the FDA that Debbie mentioned. If you take the HACCP principles and look at control points, what we're talking about is finding the control points to interrupt the chain of transmission of disease in a food handling setting. Gloves and hands form a central part of this.

There are a number of ways to transfer organisms from the food to the hands to the fulmites and back to people and back to hands and back to food. It's a nice set of loops. But in the end, what we're trying to do is simply interrupt a few of these transmission points. It's a very simple model. This can get highly complex, but all we're trying to do is define what are the practices, products, and regimens that interrupt these chains of transmission of foodborne illness.

A couple people have mentioned the Health Care Continuum Model. This was a model that we created as a coalition to try and understand from a conceptual viewpoint what are skin care antiseptic products all about. What we decided was they're really preventative products and they deal with a continuum of health care and risk, from very low risk on one side on daily use consumer products to very high risk at surgical or injection sites on the other end. In the middle, it has the food wash products. We view these as

very similar in issue to what happens in health care. I think the next speaker will specifically talk about health care and its extension to the food situation. What we see are the continual risks.

We have a couple of key issues. Number one, the situation should define what we're doing. You can't just say, this is it. This is the answer. You have to look at every individual situation. We saw that peeling shrimp is not the same as some other situations in food handling. The Health Care Continuum Model simply says you ought to look at the situation, make some judgments, gather some technical data, and decide what products and practices are needed to deal with the infection risk in that situation. And then we need a validation step on the end, which ought to be test methodologies to show that the products and regimens we're talking about are appropriate for that risk situation.

That's it in a nutshell. It's a very simple model. It says, look at the situation, gather your data, determine what you should do, and that there are no universal answers per se.

I'll expand just a bit on the types of products that are used in hand hygiene use. We have basic hand soaps, hand sanitizers, and a collection of other products.

The hand soaps, as has been mentioned, consist primarily of two types. There are the bland or non-antimicrobial hand soaps. They are both natural and synthetic. They are in bar and liquid form. These are the things you usually associate with hand washing soap and bar soaps. There are general purpose antimicrobial soaps that typically contain PCMX or triclosan. These are mostly liquid.

The key point to keep in mind here is that these are all soaps. They're all designed for washing hands. Their primary mechanism is removal of soils the way soaps and detergents normally work. You sometimes hear discussion about antimicrobials versus bland soaps, as if antimicrobials are not soaps. They all are. They're all formulated from sindad bases [ph.]. The difference is they have an active ingredient in there that adds incremental antibacterial properties to the preparation.

Then there's a specific category under USDA and the old FSIS rules of sanitizing or E2 soaps. These are products that could give you a 55 per million chlorine equivalency, kill on two microorganisms, very heavy duty soaps, by the way.

Hand sanitizers, also of a couple different types. This is the old E3 FSIS category, again, 50 parts per

million chlorine, designed as a dip, though, as a rinse, not to be rinsed off. They don't do anything for soil. They're designed for use on clean hands. These typically are alcohol with or without an active ingredient, hypochloride iodine, ammonium compounds. These are all E3-type hand sanitizers.

And part of the more recent category are the alcohol gels. These are typically 60 to 70 percent ethanol or isopropanol.

There are a number of other products that are used in various settings, including food--hand lotions, for example. They're analogous to soaps. There are antimicrobial hand lotions and non-antimicrobial hand lotions. These deal with skin care, but they also deal with issues of contamination, carriers, nutrient sources, other things on the skin.

There are recently on the market antimicrobial hand lotions. You may see this in the consumer arena. There's some regulatory action on these, a difference in opinion about whether these are new drugs or not in some people. These are typically a regular hand lotion to which someone has added an antimicrobial ingredient such as triclosan or a quat. You do not see many of these in the food service setting today.

And finally, there are antimicrobial wipes. These are simply impregnated wiping cloths that contain typically an alcohol and maybe a quat. They're designed to remove soil by a normal wipe, but they also contain a residual antimicrobial ingredient.

So those are the basic categories of products in use today. I'm doing this in very summary fashion. You find 500 or 600 E2 and E3 products listed in the FSIS listing, so there are a number of approaches that people use. The fundamental classification is how they perform on a specified antimicrobial efficacy test.

The key attributes of the hand hygiene products that are germane to today's discussion in terms of antimicrobial activity is what's their speed of action, basically, do they work fast enough in the time frame that someone would use them in the food handling setting. What's their spectrum of action--what do they kill? What is their length of action, meaning how long do they have an effect? Is it immediate or is it persistent? And someone has mentioned they need to be effective in the presence of soils, which can vary tremendously in food handling situations.

Let me summarize real quickly all the experience of the group in terms of antimicrobial active ingredients.

You need to look at the formulated products, not just the active ingredients. When a product is properly formulated, you can get broad-spectrum and fast-acting activity out of any antimicrobial active that's approved today. If you read the literature, you see a lot of scatter. This has to do, we think, with formulation effects, with test methodology, and other things. I think Daryl will have a couple comments on that in a few minutes. But, basically, if you formulate them right, they work. If you use the right test, you'll have products that are effective for use.

A difference in alcohol and chlorine in a food handling setting is they do not have a persistent effect, although you can enhance these by adding residual additives to the formula. The formulation matrix is very important. The intrinsic activity of all these active ingredients can be highly modified.

CHU is an example. You can deactivate it very easily by putting in an anionic surfactant since it's a cationic antimicrobial. There are all kinds of these things. The people who formulate these products generally know how to do this. The test methodology picks up when you have interfering effects. It's important to keep in mind you need to look at the formulation itself in terms of its effectiveness.

And finally, the use situation impacts the effectiveness.

Just a quick comparison in terms of active ingredients across the spectrum of microorganisms. Again, we're looking at the ratings for a properly formulated product using this particular active ingredient. Chlorhexidine, alcohol, PCMS, triclosan, quats, iodine, and chlorine, they are all very effective on gram-positive bacteria. They're also very effective on gram-negative bacteria. You will see conflicting reports in the literature, again, depending, I think, on the matrix effects.

Viruses is an interesting area. What we hear and see in the white paper is these things probably don't work that well on viruses. Well, in fact, there's just not a lot of test data on viruses. This is one of my points today. The reason you don't see many data on testing viruses with these antimicrobial products is because we can't make claims on viral kill. If we can't communicate the benefit of the product to the user, why would we spend the tens and hundreds of thousands of dollars doing that testing?

The fact is, there is some viral test data around and many of these products are quite effective on viruses, especially the non-envelope type. So we have to be careful

about conclusions on things like viruses and parasites when there simply is not a lot of data. Part of this is a regulatory construct, where if the rules do not permit us to make claims on these ingredients and what they can do, then we're not going to develop the data. So we're partially inhibiting ourselves in data gathering by how we construct regulation around the use of these products.

Yeast and fungi are pretty well taken care of by most of these antimicrobial products. Again, a quick summary of all these reams of test data and these 2,460 papers that we reviewed, all the internal data the companies have, basically, there are three types of data, in vitro, in vivo, and the in use. Let's talk specifically about these products.

In vitro testing, which is basically time kill and other types of laboratory tests, most antimicrobial hand washes and sanitizers exhibit a one- to five-log reduction in a standardized kill test in about 15 to 30 seconds. If they don't do that, you're probably not selling it because it doesn't compete with some of the other products on the market. This is where we're at today. These are the types of products that are on the market. They have broad-spectrum effectiveness against bacteria, yeast, fungus, to

some extent viruses. Again, the active in formula have some variation effects.

The in vitro tests generally show these things are pretty good. A lot of data that you saw earlier on the quantitative risk assessment is some of this type of data. It shows a range, typically, of peaking at one to two logs where all the data is. Most of the stuff in in vitro tests is much higher.

In vivo tests, which are actually hand washing tests using a marker organism or a surrogate endpoint, again, you see a one- to three-log reduction is typically within about one minute in these standardized tests. These are limited to E. coli, thoracia, and some viruses. We also do testing with normal skin flora. So you get a little bit of mix, but generally, you find the same thing. You can take a couple logs of organisms off the skin by using products.

The in use data is a little tricker. This is what we'd really like to have. We all want the definitive two-island epidemiology study. We're probably not going to get it in the food setting, just like we can't get it in a health care setting. So we have to take the bulk of the evidence and see what it says.

The health care data is pretty extensive. It does a lot with use of antimicrobials. It has high-risk situations. It has nosocomial infection. It also has a lot of gloving and universal precautions. So if you collate all that down, a lot of data in health care says that you can interrupt disease transmission with good hand hygiene. I don't think anybody's going to argue with that today.

However, the food studies in a field situation are quite limited. Someone mentioned the article that Femler and Ian Williams did, and I'll come back to that. We basically did that because we couldn't find any damn data. Everybody's got opinions here and intuition, but we thought it would be interesting to survey the literature and it'd be interesting to do a couple of quick studies and see whether all this stuff is directionally correct. So there is not a lot of data in a food handling setting, and you need to recognize the risk of a company publishing that data if it's done in their own facility.

I've done studies in fast food restaurants where we compared various regimens and we showed distinctly less populations on skin, but we also get into issues of there are normal organisms on people. Does a restaurant want this data published or do they want their name associated with it? So we're kind of in a tough situation in terms of use

data because there's no--the risk-benefit ratio for releasing the data is not real good for the company. We need to recognize that. But you do typically find--I'm sorry? How close am I? I'm over. All right. I will not go to that stuff.

Just a couple of quick comments. The body of evidence indicates topical antimicrobials provide an incremental improvement in infection control compared to bland soap. Particularly true, the more acute the risk association, we believe it generally applies. That's the rational of the Health Care Continuum Model.

Another point in the white paper, it seems to give the impression that antimicrobial products are inherently more irritating. This is not true. I can show you cases where we washed 100 times a day with antimicrobials compared to Ivory soap. We have done much, much better. So, again, it's all in the formulation and in the matrix, so let's be careful about general conclusions.

And finally, some of the statements concerning alcohol sanitizers, which are near and dear to my heart, I admit, are somewhat inaccurate, I think.

Our conclusions--and I'm almost done--hand hygiene is critical. I think we've all recognized that today. Appropriate products and regimens can help reduce the spread

of foodborne illness. Situational factors should determine practices and product requirements. This, I think, is the key. What is realistic for the given situation? Blanket regulation without any acknowledgement of the particular use situation probably is a failure on our part to legislate effectively.

And finally, the regulatory activity can really affect hand hygiene practices and effectiveness. We need to keep this broad perspective. If we want these things to kill viruses, then let's let people do the testing and talk about their data without regulatory limits. That's sort of the whole place we need to get to.

Let me end by one more quote. Why can't we all just get along, Rodney King, also repeated by Jack Nicholson in "Mars Attacks" and a few other times, but basically, I think there is an answer here. We kind of look at it from the middle ground. We think of regimen and situational effectiveness and that perspective will help us all reach the endpoint. Thank you.

DR. POTTER: Thanks. The next presentation is Dr. Daryl Paulson.

DR. PAULSON: I'm Daryl Paulson from Bioscience Laboratories. We've done a number of simulated studies in both cross-contamination as well as the oral-fecal route.

We've used Salmonella, we've used Vibrio, Listeria, E. coli, to track how easy it is for a food handler to pick these microorganisms up and then transfer them into other food or utensils or faucets or whatever. Our bottom-line conclusion is you can do it about as successfully with gloved hands as you can with bare hands. So the importance there is, of course, washing. It's very important to wash to get rid of those microorganisms.

Now, from the other perspective of the oral-fecal route, clearly, if a person's wearing a barrier glove and it's not compromised, it's going to contain any microorganisms. The problem is when you wear a glove like this, you put one on, or maybe even a cheaper vinyl glove, you start to perspire. Initially we thought that, well, you have E. coli or something in there and the counts would just continue to escalate, but they don't. But what they do do is it prolongs their viability than if they're just on the hand. So it's very, very important that the hand washing doesn't get trashed and the gloves are substituted for the hand washing.

Now, from a subjective perspective, we've gone out into different locales and the primary perspective of people wearing barrier gloves is, well, we really don't have to

wash anymore since we have these barrier gloves, and that's not really, I think, appropriate.

Also, I know that I had seen where someone had said there's about 43 percent holes in these vinyl gloves. We see about 23 percent, and even with one or two pinholes, an incredible amount of microorganisms can go from the hands to utensils to whatever.

Now, there are very effective antimicrobials out there, but there's also a lot of them that just don't work, that really are being peddled or sold into this area, and probably the big reason for that is there's really no requirement at the time. I know Debbie was talking about the health care personnel, and we have worked very hard in coming up with a modification of that. Instead of inoculating the hands with Serratiamarcescens, we inoculate hamburger with E. coli, have subjects more or less knead the hamburger, which puts a barrier there which is tougher than with the health care personnel for the products to move. There are a number of companies that wind up doing testing, but there's also a lot that don't.

One of the other things that we've discovered is a lot of the people in the food service arena have no way of really discriminating between products that are effective and aren't effective. The data is usually broad in terms of

the active ingredient. From a time kill study, we got 99 percent. That's really not the way that we feel these products should be evaluated. They really should be evaluated in user-simulated, just like the health care-type products.

But products that do work, for example, alcohol gels, they have the advantage of very quickly killing what you have to kill as long as there's not a tremendous organic load on the hands, and also, as soon as they evaporate, the killing is gone.

Now, as far as the chlorhexidine gluconate, I know a number of people have brought that up. That is an extremely good product, especially at the 0.75 and 0.5. The lower ends, it seems to work very well, and besides having just the immediate and persistence, you also would have a residual. The more you use it, it really stays on your hands, so you might have an additional effect there.

Previously, I thought that a number of the cax and triclosans were not very effective, but we've really come into some products that are. So it really is--and I think that's the only way you can evaluate these kinds of products.

In the end, though, I fully believe that the science is not going to pull people through. What's really

going to do it is the training. If you talk to a number of establishments, as we've done--we've done studies in the area, but it's been more low-key and a qualitative. You talk to people, the single biggest problem is people don't clearly understand what they're supposed to do. You wash your hands. Well, what are we supposed to wash our hands to? You go to the manager and says, well, wash for 15 seconds. You know, there's lots of discrepancies in there.

So what I would say is that will definitely have to be taken care of, and perhaps run a food establishment almost as if it was a GMP-type facility where there really are requirements and they're standardized. But the products are out there. They just have to be used.

Now, another thing we've done extensive testing on is the hand wash machines, and they tend to work really well. You don't need training. You just have to stick your hands in there. But the problem is the variability in the loads. Some jobs, they're very fatty, you get a lot of fat on your hands. It's very hard for those systems to take that load off. If they can, and there are a few solutions that do do that, you have a tendency, if they're using them with other people that aren't working with the fatty area, for irritating the hands, and as you irritate the hands, you

tend to get a little more microorganisms and the cycle repeats itself.

But I just wanted to leave you with that information and thank you.

DR. POTTER: Thank you very much.

The last presentation in this section will be Linda Chiarello from CDC in Atlanta. Following her presentation, we'll take a short break and then the committee will have an opportunity to address questions to all of the speakers in this group.

MS. CHIARELLO: Well, good afternoon. I have the challenge of being the last speaker in the afternoon and I'm sure you're all very ready for a break.

I'd like to thank the committee for the opportunity to come here today, but at this point, I'm feeling a little bit like a fish out of water. I'm with the hospital infections program at the Centers for Disease Control and I focus primarily on what we can do to prevent nosocomial infections and how hand washing is certainly a very important component in that area. We also focus our science on a number of other considerations, as well.

I think the deliberations before this committee are very challenging and they're also extremely important. One overlooked area is the fact that a tremendous amount of

food service delivery takes place in a relatively unregulated area, and that's in our health care settings, and we're all very familiar with the fact that numerous outbreaks of Salmonella and viral pathogens in health care settings, and if we're really talking about prevention of foodborne illness, the impact that those infections can have in morbidity and mortality is very significant.

Basically, I was asked to really talk about what we know in health care settings, and a lot of the science has already been presented today. I want to commend the FDA, Jack Guzewich and Marianne Ross, on the superb job they have done, and others who have submitted information to the FDA, on the science of transmission through the hands, what we know about hand contact, and so forth.

I was specifically asked to kind of just summarize where we stand today in our knowledge of the role of hands in transmission, the effectiveness of hand washing as an intervention, hand washing technique, and finally, to comment about gloves as an intervention.

What I thought I would do is essentially summarize by saying, what do we know, where do we stand, and what we don't know. I'm not going to go into the details of all the science that has been presented.

I think there are a couple of caveats that as I begin need to be mentioned. We know that organisms that can cause disease, primarily transient organisms, are found on the hands, and that those organisms and the significance of them can vary based on the setting in which we're concerned, whether it's health care or food service. So the organisms on the hands and their implications can vary most certainly.

But the presence of an organism is not necessarily in and of itself sufficient evidence of causation, and so the question that always arises is, is there a cause and effect relationship between hand contamination? I think we know the answer to that, but I want to summarize it.

We also have to recognize that hand washing is but one of many practices used in the health care setting to prevent the transmission of nosocomial infections, and, therefore, it's very difficult when we look at interventions to discern the single impact of one intervention, such as hand washing. We know that the practices rarely occur singly, that the studies that look at these interventions often include many components, educational and behavioral, as well as looking at hand washing practices. In some of the health care setting studies, antimicrobials have been added, so it really is very difficult to separate out what

hand washing did alone versus what the other interventions are.

Where we do tend to see the impact is more in the worst-case scenarios, where you're working with very high-risk populations in the health care setting, such as the elderly, the neonatal intensive care units, adult intensive care populations, and immunocompromised populations. That's where the impact of some of these interventions actually is best seen.

So what do we know from the science? Very clearly, the FDA white paper has summarized all the evidence on the documented transfer of organisms to and from the hands of personnel. That's a no-brainer. We have no questions about that. And we do have studies that have provided evidence implicating hands as a vehicle for transmission in a number of outbreaks.

There are experimental studies that were conducted in the newborn nurseries, which probably ethically would not be able to be done today. These were done back in the 1960s, looking at infants exposed to health care workers who washed their hands and did not wash their hands and looked at the proximity of infants to workers and so forth, and it was very clear that infants who were exposed to health care workers whose hands were not washed were more likely to

become colonized or infected than those exposed to health care workers whose hands happened to be washed.

We also know that during outbreaks, reinforcement of hand washing and other infection control interventions have been able to interrupt transmission.

So all of this information was very succinctly summarized by Dr. Lane Larson, who really is the guru in terms of hand washing in health care settings, and in 1988, she looked at whether there was an association, cause and effect relationship, between hand washing and reduction in infection. We know from the studies that there is a temporal relationship. We know that there's a strong association that infection rates are greater among those exposed to non-hand washers and that those differences are statistically significant.

As I mentioned before, it's very difficult to discern the individual impact or the single impact of that one intervention, so the specificity of the association is not there, but we certainly know that it, logically and biologically, makes sense to wash your hands. We know that there's a link between skin cleaning and reduced rates of infection, particularly during invasive procedures. We don't know that for all health care procedures. And we also

know that there's a wide variety of organisms carried on hands, and these have been readily demonstrated.

There's clearly a consistency in that association and a dose response. Cleaner hands, those that are washed more frequently or washed with an antimicrobial, are associated with an incremental reduction in the risk of infection.

So that's what we know in terms of the science, and Dr. Larson concluded that the collective evidence from both non-experimental and experimental studies is very consistent with the hypothesis that hand washing is causally associated with a reduction in infection risk. That sounds fine, but here's where we get into the difficulty of trying to assess what's really important, and that comes down to some comments I have about hand washing technique.

What we know is that the quality of technique is an important factor in hand washing outcome, the effectiveness of hand washing. What we don't know is the quantification of the effect of these various techniques and their outcome, not only in the transfer of microorganisms, but as a disease intervention, and that's what becomes very difficult to measure and I think that's what poses such challenges to this particular committee.

The other problem is that there are no standards. We don't know what the minimal acceptable number and type of organisms on the skin and hands should be. We don't know whether this is influenced by the setting in which the worker is performing. And we don't know in studies what really constitutes a clinically significant reduction in bacterial counts after hand washing. And we confound that with the variations in study methodology. So in trying to look at this issue very scientifically, it becomes very, very challenging because of these lack of standards, especially in health care.

There has been a lot done looking at the use of antimicrobials in health care settings. There's no question that antimicrobials will reduce the bioburden and the type of organisms on the hands, but when it's actually been looked at for safety in patient care, there is no evidence that in routine patient care, that the use of an antimicrobial offers any greater protection than the use of regular plain soap.

The only place where the incremental protective effects in health care settings has been observed in using an antimicrobial is really in the high-risk settings, such as nursery and intensive care units. But even there, the data is not conclusive to have a routine or a very clear

recommendation for the use of these agents in those settings.

The other area of uncertainty, I think, is the duration. What is the appropriate duration of hand washing? We know that it's very important for mechanical action and that if an antimicrobial is used, that the contact time is important, as well. We also know that the bioburden will influence those needs. To say to someone, you have to wash your hands for ten seconds or 15 seconds or 20 or three minutes, whatever, intuitively, I think, you know that that's not always necessary.

When I'm cutting up chicken in my kitchen or if I'm mixing a meat loaf and I've got my hands up to my elbows in whatever I happen to be working with, I know that the bioburden on my hands is much greater than if I've just touched a moist surface that might be contaminated. Therefore, the degree and the time and effort that's going to go into that hand wash is going to make a difference.

So there are recommendations that vary, but really, the recommendations are based on laboratory studies and may not apply in the real world setting. And we also know that if you wash your hands too long and too frequently, that there can be some skin damage that can

occur and that can be a detriment to motivating hand washing behavior.

I think there's also a number of other areas of uncertainty, and despite the fact that we have some very fine laboratory simulation studies giving us some information that provide us with a sense of direction, when we really come down to the bottom line, we don't know what impact on disease transmission the temperature of water is going to have, the drying method, hot air versus paper towels, and whether that's influenced by opportunities for subsequent touch contamination. We really don't know the role of rings or long or artificial fingernails in protecting microorganisms. Again, there's some data. But when we look at its impact on disease, risk of disease transmission, the data really is not there.

So what have we learned, at least in the health care setting? Well, we know that hand washing practices have been studied for more than a century. Samuel Weiss started it and we've been looking at it ever since.

But today, I think we have to admit there's a limit to what the science can tell us. We know that hand washing makes a difference, and I doubt that there's anyone in this room who would want to disregard that practice in any way. But what we don't know is the incremental effect

of the specific element of hand washing technique, including the type of agent known, on the outcome. We may know how it decreases the bioburden or changes the types of microorganism, but we really don't know the outcome.

We know, too, in health care that the hand washing has been overritualized, and as a nurse, I grew up in a highly ritualized practice where you had to perform the hand washing for a certain length of time and keep your hands this way and that way and every which way. We need to keep it simple. I think that's an important message, is that hand washing needs to be kept as a simple practice.

We know that compliance is low. There are many studies that look at compliance. However, even with those studies, many of them are, at least in health care settings, are set up for failure. They will, for instance, say that compliance was not achieved if someone only washed their hands for eight seconds. How do you really know that compliance was not achieved? How are we measuring compliance and what message are we giving to at least health care workers?

So we need to understand what motivates the compliance. We need to ensure that the recommendations and our expectations are scientifically supported and that they are realistic.

We believe in hospital infections that hand washing does not need to be a complicated process to be effective. It's not what is used but it's how it was done. Basically, you need three things. You need running water, you need soap, and you need a clean towel for drying the hands. We know that friction is going to remove the majority of transient organisms. We don't know the incremental impact of the remaining organisms that may be left on the risk for transmission.

We know it's important to cover all of the hand areas to the extent appropriate. We know that rinsing well and using a water temperature that's comfortable is probably more important and will foster complete hand washing, and drying well, and then avoiding the recontact of contaminated areas.

So this is, in summary, what we have learned about hand washing and health care after a century of study, and I'm sorry, I think I'm probably disappointing a number of you out there, but I think it really comes down to that, that it's a very simple kind of process.

Well, in 1987, recommendations for universal precautions were issued, and since that time, there has been an exponential increase in the use of gloves in health care settings and that has been extended to food service settings

and other areas, as well. Gloves are an important barrier, and that's another message I would not want to mislead you on. We think they're an important barrier and they have two purposes. Initially, gloves were being used to protect patients, and they're also used to protect health care workers from exposure to pathogens in the health care environment. So they do have an important role.

But here again, when we look at the science, and that's what I was asked to come and talk to you about today, when we look at the science, it's very difficult to measure the independent effect of gloves on preventing transmission, particularly of bloodborne pathogens, which is an area in which I am involved.

What we have seen from a patient care perspective is that studies have shown a decrease in infection rates in high-risk patient populations when gloves have been worn. But those studies have also been confounded by the fact that there have been other interventions that have been included. So you don't know what effect gloves had versus other areas of focusing and controlling and protecting immunocompromised patients.

It's very clear in outbreak settings or where community infections are prevalent, spread of RSV, Clostridium difficile, and antibiotic-resistant

enterobacteriaceae, gloves have had an important role in interrupting transmission in those settings versus just hand washing alone.

But when we look at probably the most important area that we perceive for glove use, and that's during surgical or high-risk procedures, when the hands of personnel will be in the body of a person undergoing that procedure, what we find is if you look at the recommendations for preventing surgical wound infections, that is a category 1(B) recommendation, which means that there is still not the level of science to recommend glove use, sterile glove use. Now, no one would not recommend it. That makes common sense, so I'm not here to suggest otherwise. But even that recommendation is based only on a strong theoretical rationale and some experimental clinical or epi studies that have been performed.

My time is up? What about the impact of gloves on occupational transmission? We know that use has increased, and we know that where they're worn, they decrease blood contact. But the impact on preventing transmission will never be discerned.

We also know that there are numerous problems with using gloves. They're not a substitute for hand washing. We know they can become contaminated, and there have been

outbreaks linked to failure to change gloves. We know they can fail.

I think the one thing I want to leave you with is what is our message and are we communicating the right message, not only to health care workers, to food service workers, to patients, to the public, but is the message that hands cannot be rendered safe and that gloves are necessary to prevent disease spread, and from a personal protective standpoint, that hands are protected and, therefore, one does not need to wash hands.

So we've learned that gloves are an important barrier, that they tend in health care settings to be over-used, under-used, and misused, and that from our perspective, scientifically-supported guidance is needed to promote the appropriate use of gloves in health care settings. Thank you.

DR. POTTER: Linda, thank you very much for a very nice presentation.

We'll go ahead and take a break now, come back, and have our opportunity to ask questions of the last panel before we go into our public comment period. Be back at 3:20.

[Recess.]

QUESTIONS AND ANSWERS

DR. POTTER: If we could start drifting back into positions and get the speakers from this afternoon's session identifiable, we'll get into the question and answer period.

[Pause.]

DR. POTTER: I hope you enjoyed your break. It's time now for the committee to ask questions of Jack Guzewich, Debbie Lumpkins, Mike Dolan, Daryl Paulson, and Linda Chiarello. So, questions? Mike?

DR. DOYLE: Mike Doyle, University of Georgia. I have a question for Debbie Lumpkins. Debbie, in your studies for the evaluation of hand wash efficacy, I notice that the bacterial pathogens you use are nosocomial pathogens.

MS. LUMPKINS: Nosocomial.

DR. DOYLE: I'm wondering if Campylobacter and Salmonella and Shigella and E. coli 0157, which are the primary foodborne pathogens, are included in your assays.

MS. LUMPKINS: No. Basically, the document was set up for health care personnel purposes. When we did the proposal, that's what we were concerned about and we were looking for a representative list that would be appropriate for hospital-borne infections. So while it does include some things like Staph aureus and some Pseudomonades, it

really doesn't address the food handler category or appropriate organisms for that testing.

DR. DOYLE: Are there intentions to make any changes?

MS. LUMPKINS: Well, I think based on the comments, we're definitely going to have to broaden the scope of the proposal. As I pointed out in my presentation, there was a meeting that was held last year trying to grapple with these issues. We're still in the very beginning stages of this, because, obviously, we're talking about huge bioburdens in some situations. But we're trying to work with people like Jack and the CDC and with industry to try and develop standards of testing for these products.

DR. DOYLE: Thank you.

DR. PAULSON: We've actually modified the health care personnel as well as the time kill and the MIC to include those types of organisms that you're discussing. They're certainly not official, but that work is being carried out. We did publish a proposed method of evaluating food handler, food service personnel hand washes in Dairy Food Environmental Sciences just this August, this past August. But we're working hard on that.

DR. POTTER: Nancy?

MR. DOLAN: Mike, the industry proposal in the Health Care Continuum Model specifies a number of food pathogens as organisms for testing efficacy of food handler products. There's a list of about 15, 18 of them, and they're all the more common--all bacterial pathogens.

DR. POTTER: Okay. Nancy Nagle?

DR. NAGLE: Nancy Nagle. I have a question. It's, I think, for Jack, and then maybe some of the rest of you can address it, as well. In your presentation, you mention that there are organisms that cannot be removed by sanitizers and cleansers off of the hand, and then the question would be, how likely are they to come off on the food, or is there any information of how well they can be removed by the food?

MR. GUZEWICH: Thank you, Nancy. I think you're referring to the resident microorganisms as opposed to the transient. The resident microorganisms, for the most part, are not pathogens. Carnal bacterium, and I can't think of the other group that are normally involved, they're in the sebaceous glands. They're in the deeper layers of the skin. As you wash more, you bring some more of those to the surface, but you'll never get them all off.

So in a lot of the studies, when they continue to recover microorganisms, they're recovering non-pathogens

either from the infection control perspective in the health care setting or from the perspective in food safety. There are organisms there, but they're not pathogens--

DR. NAGLE: Right, but I think in both the presentation and in the reading that we had, we mentioned Staph aureus as one of those organisms.

MR. GUZEWICH: Yes. Staph is the one. Staph is the one that can still be there, that's right. The other ones are not. You're right. Staph can be there, although most of the Staph are not positive, but some of the Staph there, they are positive. In--the studies tend not to quantify always the organism. They just looked at total number of organisms recovered, APC kind of stuff, rather than how many Staph were among the bugs that they were getting off.

But the inference generally is that the Staph frequency on the hands is not that great, because most of the time it's probably non-pathogens, although it always could be some pathogens.

Do you want to add to that, Mike?

MR. DOLAN: Yes, I think that's correct. The primary concern from an infection control standpoint are the transient organisms. I think it goes back to the original question of can skin be sterilized. Even on a surgeon's

hands with highly efficacious products and routine use, you can only get the organism levels down to a certain point. You're never going to stop all of them. But from an infection risk standpoint, when the levels are low enough, I think the infection risk is also very low, and then you get a regrowth of normal skin resident organisms over time. In fact, they start regrowing fairly rapidly after you kill them off.

DR. NAGLE: Right. I was going to ask, isn't it true that it isn't really a good idea to try to get it down to zero anyway because those organisms, they're needed there in the skin, aren't they, or--

MR. DOLAN: Yes. I think other than a strictly invasive procedure, you really don't want to kill off all the normal skin organisms. First of all, you would tear your hands up so badly you'd become non-functional. And secondly, you would lose the protective function that those organisms play in normal skin hygiene. The issue is how low is low.

DR. POTTER: Jim?

DR. DICKSON: Jim Dickson from Iowa State. It's just more of a comment. As you folks develop data on new pathogens, if you will, foodborne pathogens, if that information could be published in a comparative fashion to

the standard organisms that have been used over the years, for example, if Shigella is less sensitive than organism X and more sensitive than organism Y, that might provide some additional use for previously published data. That is, we could make comparisons between what's already in the literature versus these other organisms that have not been published.

DR. POTTER: Earl?

MR. GUZEWICH: That's a good point, Jim. I'll just add to that. One of the problems we had in reviewing this is that there are studies that were done over a long period of time and by many different studies with many different methods. We couldn't compare them now because of that problem.

DR. LONG: This is for Mr. Dolan. Earl Long, CDC. Can you tell me what the inaccurate statements about the effectiveness of alcohol preparations are?

MR. DOLAN: If I can restate the question, it's additional amplification on my comment about inaccuracies relative to hand sanitizers?

DR. LONG: Yes.

MR. DOLAN: Several things. One is this issue of regrowth and finding more organisms after you use a hand sanitizer than before. I think what you're seeing is

discussion of the variation in the test methodology at very low organism levels. I believe it is clinically completely irrelevant. There are a number of studies that show the same effect with hand washing, that you can actually get more organisms on your hands after a second hand wash. Does this suggest you're not going to hand wash? Probably not.

There's also some comments about the composition of the products containing surfactants and other skin-damaging ingredients. It's just the opposite. Most of these products contain humectics and skin conditioners. We've got data that says you can use a hand sanitizer 100 times a day and your skin condition does not deteriorate.

So I think, generally, there's a negative perception of these products and their application in the food service setting that I think is inaccurate.

DR. POTTER: Mike Robach?

DR. ROBACH: Mike Robach, the County Group. This morning, we talked about the role of viruses in illnesses related to food handlers, and this afternoon, we seem to have shifted gears and talked a lot more about bacterial pathogens. I have a question regarding the effectiveness of the interventions we heard about this morning on destroying or at least reducing the incidence of viruses.

MR. DOLAN: Sure. I think you can view viruses and bacteria as small particulate matter. So any time you have a detergent matrix used in a hand washing sense, you will reduce the number of organisms on the skin simply by the washing effect.

Now, there is not a lot of data that applies to viruses. Most of it has been done on bacteria. Sitar [ph.], for example, in Canada has done some hand washing studies with viruses showing that you can take a fair amount of them off with water. You can take a few more off with an antimicrobial product. And you can kill some by using certain antibacterial actives. So you have to distinguish between the physical removal of viruses from the actual chemical inactivation of a virus.

I think there's not enough data to make broad-scale conclusions about the effect of antimicrobial products on viruses on skin. The directional indications are that the products can be effective against a fair number of viruses. But again, there's no standard methodology. I've seen no field data at all on this, and it's an area that we need some more research.

MR. MILLER: No. I think that was the point of my comment. I think there seems to be a--we've got 40, 50 percent of these diseases associated with food handlers

associated with viruses and we have circumstantial data but no real scientific data on the effect of these interventions on viruses.

MR. DOLAN: I think you have an additional complication because the infected dose of viruses is probably a lot smaller, particularly for some of the more virulent pathogens. So you may have to take them to extremely low levels before you reduce the risk below a certain threshold.

DR. POTTER: Steve, did you have anything to add to that?

DR. MONROE: Two good points there. The first one is low infectious dose. With Norwalk virus, the best available data suggests that as few as ten microorganisms are enough to make someone ill. So it's very difficult to measure virus at that level.

And just overall, the methods for detection of the viruses, particularly non-culturable viruses like Norwalk, have not existed, and so there was no possibility of doing the kinds of quantitative assessment, and now, the only way to do it would be by using the molecular RT-PCR kinds of detection, which raises the issue of are you measuring infective virus versus non-infective virus. So it still, even today with our newest methods, would be difficult to do

those studies and be completely confident that you're measuring removal of the virus.

DR. POTTER: Thanks, Steve.

MR. GUZEWICH: One thing I might add on that, too, that may not have been clear when Dale Morse mentioned it this morning, the data in New York showed a tremendous number of outbreaks that no doubt were Norwalk-like, okay, and when the regulation went into effect in New York in August of 1992--I was still working there at that time--a lot of epidemiologists said, well, you should see a decrease in the number of outbreaks associated with that because you have this regulation in effect. Unfortunately, because you pass a regulation doesn't mean it's implemented. That's the way they work.

So we continue to have outbreaks in New York, even since I've left, of course, and the outbreaks there were always in cases where people were having bare-hand contact with the food. They did not have any outbreaks where they did not have that going on. So it continues to be that the fundamental problem is getting people to comply with it as opposed to the other.

So one of the problems we have here is trying to get an epidemiologic study as well as the field thing that Mike was talking about, along with the more laboratory-based

studies to show the effectiveness. It's anecdotal. It's not great bench science. But anecdotally, it does seem to be the case that when people don't touch the food, typically with gloves or they can use the tongs or whatever, they weren't seeing any outbreaks in those cases. When they were having the outbreaks, it was clearly people had the hand contact with the food and they were sick.

DR. POTTER: Bob Buchanan?

DR. BUCHANAN: I'm not sure who to direct this question to. Staying away from the ill worker at the moment and fecal-oral transmission, I want to focus on the other sources of organisms in the food service environment. If I was to do a real good job of washing my hands and put a glove on one hand and left the other hand bare, after an hour of working in a food service environment, would I have the same types of organisms on the glove versus the bare hand and would it be approximately in the same number, and would I be more likely to transfer organisms that are present on those hands, bare versus glove, to a ready-to-eat food if I picked it up?

DR. POTTER: Nice question, Bob.

MR. GUZEWICH: Quick and dirty, the thing here is we agree that there probably wouldn't be much difference in the bugs. You would have picked up the same ones. You

would have a chance to transfer the same ones, generally speaking.

DR. BUCHANAN: So the primary concern about gloved and non-gloved hands is still focusing back on the ill worker, okay, but in regard to transfer of microorganisms that are picked up within the food service environment, other than that, you're not indicating a big difference between glove versus non-glove?

MR. DOLAN: No. In fact, we looked at gloves in a number of transfer situations where it could transfer to utensils or to paper or to food and back to hands. Our conclusion was that gloves were the pseudo-skin in a food handling situation. They behave very much the same in terms of microorganisms. They can live on the skin. They can transfer off of gloves just like skin. The issues are very, very similar. The only difference is that if you go long enough, and depending on your starting state, your resident organisms may have some impact on that population.

DR. BUCHANAN: Now, if the risks associated with both of them are approximately equivalent, what risk reduction would you achieve with the appropriate use of utensils, which we haven't discussed at all?

MR. DOLAN: I think it's a question for quantitative risk assessment.

[Laughter.]

MR. DOLAN: It's certainly not in my domain

DR. SEWARD: Bob, this is Skip. I just want to say that our work shows the same thing, is if you have gloves on or bare hands, the in-house work that we've done illustrates that there's really no difference between those two. And in reference, whenever you can use a utensil, when it's practical or feasible to do that, then that's a good alternative, because then neither your hand nor your glove is coming in contact with the food. So there are times when that's a superior method, and that's where, when they were requesting some flexibility, I think that's what they're talking about, is in certain circumstances, it's great to use a utensil where you can do it. That's probably best in those circumstances to do that.

DR. POTTER: David?

DR. ACHESON: Given what we heard in the last presentation about the lack of data supporting the value of antimicrobial agents over plain soap in terms of health care environments, one concern I have is the generation of antibiotic resistance using antibacterial agents indiscriminately, and I was wondering if the panel could comment on that.

MS. LUMPKINS: Okay. In January of 1997, I believe--I'm not good with my dates today--we asked one of our advisory committees--we were evaluating the basic underlying concept behind the Health Care Continuum Model. Basically, at one end, you have consumer use products that are low impact but can affect a lot of people, and at the other end of the spectrum, you have high-risk situations where the impact is great but smaller numbers.

One of the things that we came across in the literature were the presence of bacteria bearing plasmids that carried both resistance to an antibiotic and to an antiseptic, which is something most people thought wasn't going to happen. We gave this information to our advisory committee and basically what they came down to is, right now, there doesn't seem to be a great deal of cause for concern because most of our data is laboratory generated. We haven't seen any evidence that these organisms occur in the wild, but that it was a situation that really bore some watching.

They recommended that we set up some kind of surveillance system so it's something akin to maybe what the CDC does with the nosocomial pathogens to try to get a handle on this, and basically, that's where we are.

DR. POTTER: Alison?

DR. O'BRIEN: This goes back to another question for, is it Dr. Morse, if he's there, and this relates to the New York no bare hands ruling. Under the circumstances of no bare hands in New York, how did the retail establishments comply with that? Did they all begin to use gloves? Did they do it through gloves or through some various means to make the effective dent on some of the viral illnesses?

DR. MORALES: I have to be the token figurehead to talk on the basis of State experience? The honest answer is the epidemiologists investigate the outbreaks and the food, the environmentalists, help more to control them.

The regulation and law was phased in over several years. It wasn't just August 1992. There were several steps, the Syracuse experience where they had used the glove rule and then modified it to no direct hand contact. So there were a number of other counties that implemented that over time, being sort of out in front. Then there were some training exercises to try to reduce hand contact in 1990. So there was a different level of involvement. Some of the big agencies, food companies, actually started doing some training programs, anticipating that there was going to be a State regulation. So it wasn't just August 1992 that they started to do this. So it was a variable phase-in that took place. Jack?

MR. GUZEWICH: Like Dale said, it didn't happen overnight, overnight in terms of getting all the health departments on board to apply it as well as the industry. So it wasn't a throw-the-switch kind of a thing.

But I think it's fair to say now that the industry has the ability to implement it always in New York. They don't always do it still. I mean, there are places that just aren't in compliance and the inspectors, if there, find noncompliance routinely, unfortunately.

But even where there are tasks that are difficult to do, people adapt and learn how to do them. And so initially, some of the tasks were thought to be just not possible. I can't do this task wearing gloves, since gloves are the thing that you're getting down to in your question. There's tongs and utensils. They were doing all that kind of stuff, too. But over time, they adapted and learned how to do it and they were doing it. They either used a different kind of glove or they had to modify their method a little bit.

One of the other concerns was that the rate of productivity would go down, but I think over time, once a person gets adept at it, they can even do some of the harder tasks.

I guess one of the holdouts we had was a large famous school of culinary arts, that I won't go any further naming, but some of you will probably figure out. Some of the professors of that facility were more resistant. Some of them didn't have English as--well, anyway. But suffice it to say that they came around, too, and even in operations that are pretty tough to do, baking operations. There are some things they do in baking operations and stuff that are very tough, as well as just in the other food operations. And they adapted and learned to make them work.

So it is difficult. It's a change for people. It's other than the way they've done it for a long time, maybe their whole careers and the way they were taught to do it and the way they see everybody else do it. But, by and large, they adapted and learned how to work with those things on. That's the question you're asking. But they still have noncompliance.

DR. O'BRIEN: That was a great answer and you did include what I was asking, which was, was it gloves primarily, but it sounds like it was everything that worked to not use your hands directly.

MR. GUZEWICH: Exactly.

DR. O'BRIEN: Okay.

MR. GUZEWICH: From the get-go, that's what it was. Everybody calls it--that's what Mike even quoted me today--it's not a glove law, it's a no bare hand law, quote, Mike Dolan this afternoon. So they've certainly used spatulas, tongs, deli wraps, et cetera.

DR. O'BRIEN: And probably gloves that fit better than the ones that are being circulated here.

MR. GUZEWICH: No, some of them--those are the least expensive ones and some of them tried that, but they found that they're too clumsy to use, that they usually had to go to other ones if they really wanted to be able to do the job.

DR. O'BRIEN: Thank you.

DR. POTTER: Stephanie?

DR. DOORES: Getting to that issue of everything but the bare contact with hands, what's to say that people aren't using utensils for hours on end without cleaning, they're at room temperature or warmer, there's cross-contamination, and things of that issue? How is that going to be any different if you're just, in a sense, transferring the issue from using hands to using utensils that you're not taking care of? It's just trading problems, isn't it?

MR. GUZEWICH: Well, as Steve Grover said this morning, there is no magic bullet about any of this, and as

I was out getting my soft drink here at the break, one of our other speakers this morning pointed out that the handles of the scoops in the ice had been rolling in the ice, so you had to reach in and contact the ice if you were going to pick up the ice scoop out there 15 minutes ago. So you always have those problems. People can misuse any intervention you have.

These are all--the problem with this whole thing is it's all people-dependent. You can't build people out of any part of this equation, and we're trying to stay in this discussion today and tomorrow on the science issues and not on the compliance and the people issues, which is very hard to pull these things apart. Most of the discussion is more on the behavior issues rather than on the hard science issues. But those behavior things can happen and people can certainly do anything you can come up with inappropriately and in ways you can't even imagine.

Since for some reason, Mike wasn't going to identify his colleague that talked about the gloves, going to the toilet and not, that was Dr. Dean Cliver, who a lot of you know, and he's right. You should wear them going into the bathroom and take them off before you come out.

DR. POTTER: Jim?

DR. ANDERS: Jim Anders. I realize that we're talking a lot about human behavior here, but still, human behavior has got an effect on, for instance, hand washing. You're talking about--some of the discussion today has been that if we could have hand washing, then we wouldn't have to have gloves or we wouldn't have to have antimicrobials.

Well, the concern is, I did an experiment during our last break because Mr. Dolan said that it would take 15 to 30 seconds to use an antimicrobial. So I decided to just see how long, if I normally wash my hands, how long that actually took, and, by the way, I had to stretch it to get to ten seconds with soap and water. When I actually timed it, then, to go to the antimicrobial, where we're going to go to 30 seconds, I mean, that is an exorbitantly long time for washing your hands, which the normal person doesn't do, I don't believe. At least, I certainly don't do it. And by the time I got done, it was almost a mechanical thing with your hands.

So I don't see how you can rule out human behavior here when you're talking about science, because you're saying if washing hands works, it only works if you wash your hands the right amount of time. So I guess I have a question on how we can exclude that.

MR. GUZEWICH: It ain't easy. Those are the risk management questions that FDA has to deal with and the Conference on Food Protection has to deal with, as well, and what we're looking for, we're hoping to get out of you all on the advisory committee is your view on the scientific issues. We could have had a whole afternoon meeting on the behavioral issues, as well, but that gets beyond the scope, and we're trying as best we can, I know it's very hard to do, but to stay on the others. In other words, from the scientific point of view, there are three interventions, three hurdles, three multiple barriers, and scientifically, what are the merits of those three from that perspective? Understand the behaviors are in there and the other problems are in there.

DR. ANDERS: My point, then, would be that if people aren't going to wash their hands so long, then I would recommend scientifically that they use not only washing hands but then gloves and everything else under the sun.

DR. POTTER: Dane, and then Cathy.

DR. BERNARD: Thank you. Dane Bernard. We heard this morning from Steve Grover and a few others and we heard this afternoon, I think, from Mike Dolan about alternative strategies, food service establishment-based, no set

formula. I'm wondering, Mike, if you couldn't enlighten us, or especially me, a little bit more about how that scenario would work. What are we talking about there in terms of what goes on in an individual establishment being driven by the work that that establishment does or the structure of the establishment?

DR. DOYLE: I can do it from a theoretical level, Dane. Actually, it was an interesting restroom conversation I had on this topic a few minutes ago.

DR. BERNARD: I'm not sure I want to hear all those details.

DR. DOYLE: The question was--let me rephrase the question. It was, if I had a restaurant, what would I do without any regulatory constraints, knowing what I do about infection control? I think what I would do is take a HACCP approach and find out what the critical control factors are for transmission of organisms and deal with them specifically, situation by situation, in a restaurant. I believe part of that would be gloving and barriers. Part of it would be hand hygiene and sanitizing. A big portion of it would be positive motivation of the workforce to practice effective hygiene, not just on hands but on utensils and other things.

So I think what you're talking about is you need to look from a HACCP context, what are the real serious risk issues and let's deal with those and let's not get caught up in the small ones. If something isn't a control point or isn't a critical control point, let's not waste a lot of time on it. Let's concentrate on the big ones.

The concern is that you try and pass one set of standards that applies to everything. I think we've heard a number of times that there are diverse food handling situations and each of them has its own intricacies. It may be that one approach, so as no bare-hands contact, is the best for all of these. It may not be. In my personal view, not speaking for anyone but myself, you have to look at every given situation and decide what the best practice is.

I agree, Dane, you can't eliminate the behavior part, because the technology and the humans interact all the time. So we have to find that combination that reduces risk to the minimum level, and we're going to have to decide what an acceptable risk tolerance is. We're not talking about a zero incident rate here. That's not achievable from anything I know about. So we have to concentrate on the big, most important ones and get that done, and then when we're done with those, we'll go to the next level. Does that answer your question, Dane?

DR. BERNARD: I think so, yes.

DR. POTTER: Thanks. One last question, Cathy.

DR. DONNELLY: I'd just like to ask Bob Buchanan's question maybe as a follow-up in a different way. Bob didn't want to include the ill workers in his hypothetical scenario of side-by-side, washed hand and gloved, but is there any evidence to suggest that for those individuals that are either carriers of Salmonella, Shigella, Hep A, what have you, that having a glove or washing your hands effectively reduces the transmission of those agents to foods?

MR. GUZEWICH: Very limited data. That's the experience we had in New York, with the Hepatitis A in Syracuse and the situation since the regulation has gone into effect. We have had no outbreaks for people who are complying with that, and I know that Massachusetts has had a similar experience, and other people who have been investigating these outbreaks, they continue to see outbreaks associated with these agents that are basically fecal-oral agents. They continue to see them oftentimes when the people are ill, clinically ill, demonstrably ill at the time of their involvement, spreading their organisms, but always in cases where they have had bare-hand contact

with food, never in cases where they have not had bare-hand contact with food. That's the best answer I can give you.

DR. DONNELLY: Can I just follow up, Jack? I noticed in the New York data, there were 25,000 immunizations for Hepatitis A. Does that play a role, as well?

MR. GUZEWICH: Okay. Dale is referring there to what was the situation in Onondaga County between 1987 and 1992, I think. Those were immunizations that were provided to people who had been exposed to known positive workers. It was situations where a person's illness was reported by the physician or the clinical laboratory to the health department. The health department in its routine follow-up found that that person was employed in a food setting. When an interview there determined that that person's job responsibilities included touching ready-to-eat foods, therefore, they have a population at risk and they were going to have to go out with a classic announcement, anybody who had eaten in this place in the following days and eaten the following foods needs to get a shot. It was those kind of scenarios. So they knew they had a population at risk. They knew they had an exposure to Hepatitis A. So it wasn't just everybody in the community, it was those finite situations.

DR. DONNELLY: But did New York State explore the risk versus benefit of doing immunization for food handlers for Hep A?

MR. GUZEWICH: They were going with the APIC recommendation, which today doesn't see it cost effective to do that. They've gone with what APIC has said on that. I'm not there anymore, but that's still the same thing, right, Dale? I don't like to talk for New York today because I'm not New York today, but are they still going for--they're not recommending immunization of all the food workers in New York State for Hep A?

DR. MORALES: Well, the use of immunoglobulin rather than immunization, small point, but there are situations--like in Syracuse since then, there have been one where a food worker did have direct food contact and was incubating and there was a clinic. So if we have evidence of direct exposure within two weeks that we give immunoglobulin, we still do that, and that's partially because we've had 16 outbreaks in the 16 years. So we have had a large number of outbreaks. So based on that track record, we've still used it, though it's getting more difficult because there's a shortage of immunoglobulin. So I think that will have to be revisited in the difficulty of getting immunoglobulin.

DR. POTTER: Okay. I'd like to thank the panelists. This brings to a close the question and answer period. Perhaps at some point, a distinction between post-exposure passive protection and pre-exposure active protection from the vaccine ought to be clarified.

PUBLIC COMMENT

DR. POTTER: Let's go on then to the public comment. The public comments will be limited to five minutes each with a short period of question and answer for each one. The first presentation is by Dr. Amy Wong.

DR. WONG: Thank you. Can you hear me? Thank you. I just want to use the next five minutes to briefly share with you some of the data that we have generated in looking at the efficacy of hand washing on inactivation of four common foodborne pathogens, Salmonella enteritidis, E. coli 0157-H7, Staph aureus, and Bacillus cereus, and also looking at the pathogen survival and potential for pathogen transfer from hands and gloves.

What we did with the hand washing experiments, and this will be very brief since I only have five minutes, we used some subjects that we just corralled from around our department and we inoculated on each of their eight fingers, excluding the thumbs, ten microliters containing about 1,000 CFUs of each of the pathogens and then spread it over the

tip and let the hands dry for two minutes. What we noticed was that depending on the subject and also the relative humidity of that particular day, the hands dried, or the inoculum dried at different rates, and by two minutes, a lot of times, you would still see some moisture on some of the fingers, but in some subjects, the inoculum was totally dried. So we noticed that what happened, when we covered the organisms, what we did was we allowed them to press their finger on an agar plate and spread it and then incubate the plate and count the number of organisms after 24 or 48 hours.

What we noticed was that the drier their fingers after two minutes of air drying, the lower the recovery level, and you can see this. In the first column, where we didn't wash their hands, it was just inoculum of the four different pathogens on the different fingers. We recovered anywhere from about two percent to ten percent of what we inoculated to begin with. Now, this doesn't represent all of the inoculum remaining on the fingers. It's just that after one touch, what can be recovered from the fingers, and we took that to be an indication of what might be transferrable from a contaminated finger to a food or a utensil, what have you.

Then we went on and with the inoculated fingers also washed--it's three different types of washes. One was just a plain water wash for 20 seconds, as indicated in the FDA code. This is just mechanical action with water. We also used a soap, which is a liquid soap with an antimicrobial in it, and also a hand sanitizer, an alcohol-based hand sanitizer. With the water wash and the soap wash--after the soap wash, we also rinsed the fingers with water and then dried the hands with two paper towels. With the hand sanitizer cleaning, basically, we just let them rub until the hand sanitizer evaporated and there was no drying afterwards.

So as you can see, with both the S. enteritidis and the E. coli 0157-H7, even just mechanical washing with water was able to either inactivate or remove whatever organisms that were on the fingers. We couldn't recover anything, and that's the same with the soap washing, also the hand sanitizer cleaning.

With Staph aureus and B. cereus, we were able to recover a little bit of the inoculum that we had inoculated to begin with, anywhere from 0.2 to 3.6 percent. And with Staph aureus, we know that there are some Staph aureus that are normally present in the resident flora of fingers, so

that might represent some of what's normally originally present on those fingers, too.

So with the transient flora, the contaminating pathogens, those are pretty easy to get rid of if you wash your hands properly. This is very different from what is normally present on the fingers themselves and this is using just having the subjects touch the agar plate before washing and then also after washing with soap, water, and hand sanitizer that they had done before the inoculated studies.

As you can see, in many instances where there was soap and water wash, the counts that we recovered after washing were, in many cases, were a little bit higher than even before washing, and this echoes what some of the earlier speakers have mentioned before. When you wash, your resident flora, sometimes you expose the microorganisms that are in the deeper layers of your skin. So that's not surprising. With the hand sanitizer, we're able to reduce the number of organisms normally present on the hands by anywhere from 92 to 98 percent. That's indicated on this table.

Then we looked at a few different brands of gloves that are indicated by brands A, B, and C here on the table and did the same thing, inoculated the fingers on the gloves, not the thumbs, with ten microliters of the

respective pathogen and looked at recovery again, on touching the fingers on an agar plate and looking at recovery levels, anywhere from zero minutes up to 40 minutes or, in some cases, a little bit longer.

What we noticed was, again, as with the fingers, with the gloves, the faster the gloves dried, the lower the recover rate of the organisms that were inoculated into the fingers. With the three different brands of gloves, glove A dried the fastest, and you can see on the bottom the average drying time was 31 minutes. By 31 minutes, we could see that the inoculum was basically dry, visibly dry. Whereas with brand B, it took an average drying time of 63 minutes before the ten microliters of inoculum looked visibly dry. And brand C was a little bit in between. Forty-three minutes was the average drying time.

With these gloves, if you look at all the pathogens of the first row, where it says zero minutes, the recovery level ranged from anywhere from about 53 percent to about 80 percent of what we inoculated on the fingers, and after 40 minutes of air drying, it ranged--the lowest recovery rate was in brand A, which had the fastest drying time and it ranged from about five percent to about ten percent for E. coli, whereas with brand B, after 40 minutes, the gloves were still visibly wet and you can see we were

able to recover quite a high percentage of the inoculum that we inoculated. It ranged from 34 percent to about 53 percent for Staph enteritidis.

After drying, the last row in each of the columns, for brand A, after dry would be only 31 minutes, so we don't see an appreciable difference for brand A after drying for 31 minutes, as opposed to leaving it longer, for 40 minutes. The recovery levels were very similar. But with brand B, as you can see, 40 minutes, and after drying for 63 minutes, there's quite a dramatic drop in recovery levels of the pathogens remaining on the glove fingers.

So, just to quickly summarize what I've just shown you, the rate of drying appears to be a major factor in affecting the recovery of pathogens from hands or gloves, and inoculum on hands dried quite a bit more quickly than on gloves. Within two minutes, a lot of people's fingers looked already dry, whereas with gloves, depending on the brand you use, that particular brand B had a lot of texture on it and that inhibited the drying rate quite a bit, or prolonged the drying rate quite a bit. So the gloves took anywhere from 31 minutes to 63 minutes before all the inocula were visibly dry, and the longer it took the gloves to dry, the higher the recovery rate of the pathogens that we inoculated on the gloves.

As almost everybody today has shown you, washing 20 seconds with water, soap, or hand sanitizer was quite effective in inactivating or removing most of the pathogens for transient organisms that were inoculated on the fingers, whereas normal resident bacterial flora was quite recalcitrant to removal by soap or water but could be reduced substantially by hand sanitizer. As the previous speaker alluded to, most of the normal flora is not pathogenic, except for a few like Staph aureus, so it's not a major concern for all practical purposes. Thank you.

DR. POTTER: Time for questions.

DR. O'BRIEN: I have a question for you. If you did the finger dip and then put the glove on and then put the finger on the plate, which is what we're talking about here, the food worker carrying contamination to the food site and not washing properly, if you then put the glove on and touch the plate, how much transmission did you get there?

DR. WONG: We haven't done that.

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

DR. WONG: Yes.

DR. POTTER: Okay. Thanks, Amy.

The next presentation, Noel Segal.

[No response.]

DR. POTTER: Lacie Thrall?

MS. THRALL: Is this adequate, to be here rather than up there? My name is Lacie Thrall. I'm from a company called Food Handler. I am from a glove company, so we wanted to be represented here and make a few brief points that we think we'd like to put in for the record here.

Specifically, the things that we wanted to mention here, as a glove company, we support overlapping and dual public health controls for handling ready-to-eat foods. One of the controls certainly is hand washing. Number two control, an additional barrier is good assurance at least against foodborne contamination, whether it's a glove, a hand sanitizer, or an antimicrobial. We believe that two barriers certainly is better than one barrier, and using the behavioral concerns that we talked about earlier.

The second point is training and education. In common sense terms, the food worker is essential for hand washing practices, all barriers and methods of intervention to prevent cross-contamination of ready-to-eat foods, but they're not foolproof. So we want it to be practical, but that's a tough part of it. The reality is that managers also have some responsibility to catch poor practices. It's the human factor, just what we talked about here.

There are educational issues. My background is from public health. I was a public health inspector for 17 years, so I watched that. I worked in restaurants for several years, also, and I think that's a real concern here. There is a false sense of security with every intervention if it's not monitored.

As mentioned, similar hand washing practice and education issues are faced in the medical profession, so I think we're getting some information back that we have those same problems in food service, but we have less education in food service than we do in the medical industry, so that human factor is very important.

The third point is task-specific interventions. This was brought up a few times in the discussion already. Each intervention, such as the use of gloves or a utensil or hand sanitizers, is task-specific to each food processing step of a menu item. In our training programs, we find that many very skilled chefs don't understand when and what foods are considered ready-to-eat foods, no offense intended by saying that.

There are certainly benefits and limitations to each type of product used, each type of glove used. Somebody mentioned a nitro glove versus the gloves that Steve Grover showed here. So there is a big difference in

those types of things and we have to understand that in making a determination as to what is best.

The last point is quality of an effective intervention. I think we had some information on that, also. We encourage the committee to consider the quality characteristics necessary of the products used for food contact barrier interventions, i.e., quality manufacturing standards for the glove industry for food contact. There are some FDA standards related to medical gloves. However, across the board, sometimes we get what we call B-grade gloves that are used in the food industry because they don't meet the medical standards as far as the FDA is concerned. So that is another issue that we think is very important and we're very proactive about the quality standards necessary for a glove to be used in food service as well as the medical industry.

We are very positive about the food code and the advice that has been given there, the alternative interventions and the language that was changed in the Conference for Food Protection. I think the main thing is the training from every angle for all concerned, which involves the food industry, the workers, managers, the culinary pros, the consumers, the regulatory. Also, I find, being a past regulator, I find many regulators don't

understand the differences between a different type of glove and when it should be used and when it shouldn't be. So all those things are necessary to understand the issue.

Our interest is to study the appropriate use of gloves and hand washing with the food industry in disease prevention. So those are some of my points that I think are most important as far as from a glove company standpoint.

DR. POTTER: Thank you very much. Questions for Lacie?

[No response.]

DR. POTTER: All right. Self-evident stuff.

Barry Michaels from Georgia Pacific.

MR. MICHAELS: Hello. I'm Barry Michaels. I'm staff microbiologist and also a product development manager at Georgia Pacific.

I wanted to try to address some of the questions that came up that I thought maybe could be answered a little more adequately. There is an awful lot of data. The big problem is, unless you spend a lot of time analyzing similarly conducted experiments, it's hard to draw conclusions.

But when we looked at the hand washing process and the effectiveness of the hand washing process, we found that, generally, you could say that hand washing with soap

or without soap, rinsing, and then drying, each have a part to play in the process. It became additive. In other words, if the hand washing process yielded an 85 percent reduction and the drying process studied alone yielded a 90 percent reduction, which, in fact, not only we but other investigators have shown, then the end result is that two to three logs described by some experimenters who have put the two together. Further, if you combine that with the use of an instant hand sanitizer appropriately, you could expect additional reduction. But realize, the easy to remove, the soil microorganisms, are the ones that normally instant hand sanitizer studies are used to evaluate, so you're not going to get that big of an additional effect.

One area that I think is worth discussing, because it has been discussed very heavily, is fingernail brushes and fingernails, and also the number of organisms on hands. Hands, resident flora counts are between two and ten million, and once you get down to a virtually sterile stage or low numbers, let's say 200,000, it'll take a week or so before those populations are reestablished. So there is, and I think some folks have described it, you can knock those numbers down and keep them down with repeated hand washing. Repeated hand washing is effective.

At the same time, 95 percent of the microorganisms on hands are found around the fingernails or under the subungual space and the nail fold is a great area, and it's a great area that collects a wide assortment of microorganisms that are picked up from the environment, fungi and viruses and the like. Feces contain between ten-to-the-seventh and ten-to-the-tenth of microorganisms and viruses, Salmonella with affected individuals at the peak of their infectiousness.

A couple of investigators, DeWitt and Pruckshank and Humphrey [ph.], have shown that affected food handlers, if they wash their hands, are not necessarily at risk, and I think they made a fairly forceful case analyzing counts on hands. So I think that, combined with a good number of instances where effectiveness has been shown--Methanager [ph.] showed in a day care study that with vigorous hand washing as opposed to regular hand washing, diarrheal diseases were reduced by 50 percent and respiratory diseases by about one-third. So we know that there is an effective level.

The low infectious doses present with many of these microorganisms, I think, also lend to the importance of additional contact surfaces being a route of transmission. Especially when you have ten-to-the-tenth or

ten-to-the-seventh infectious particles in feces, I think washing hands and toilet areas are extremely important.

I think we saw that gloves are slightly different in the die-off rates and die-off has a lot to do with this window of opportunity. In fact, there have been some good transfer studies done in which, I think, 85 percent of the organisms were able to be transferred from hands to a plate, let's say, immediately, if you waited before the drying period. So we know that transfer is good. But the media is important. Is it a sticky media? What's the reality of that media? And also, is there an increase in numbers that's going to occur? Competition on the hands is important, and if we start killing off the resident flora, not only do we run the risk of losing that competition, but that's where colonization from the gram-negative group, gram-negative folliculitis is also known to occur.

One thing that has been shown with colonization, skin damage is an important part of that. So we have to tend for the need to the hands and not damage the skin in whatever means we use for hand washing, to achieve hand washing effectiveness.

DR. POTTER: Thank you. Questions for Barry?

[No response.]

DR. POTTER: The last person who asked to present, James Lee Budd. If others would like to make comments, please check in at the table.

MR. BUDD: Thank you. My name is Lee Budd. I'm the Director for Risk Assessment Services with Health Minder, which is Sloan Valve Company and a Sloan Valve initiative.

I have some synopsis here of some of our presentation that I'd like just to pass out, and hopefully, I'll be finished with the presentation before you get the synopsis.

We submitted our remarks earlier and we've provided two appendixes, one of which is the survey that we did in cooperation with NIHA, and the other is the draft report from Dr. Schaffner, Becky, and Dr. Chen regarding the role of spigots in hand contamination.

But, anyway, we were participants at the Conference for Food Protection and we came away realizing that we needed to know more about the science in terms of people-to-food contamination--spigot is a common contaminant--the role of education, supervision, and behavior change, and the relativity of the food code regulations in this area, and that's what I wanted to talk

about, because we think there's some engineering and design considerations here that could help promote healthy hands.

So what we did was we studied security tapes of food handlers behind service lines and we convened focus groups of workers and supervisors. We talked with engineers and kitchen designers. We worked with NIHA and we provided a research gift to support risk analysis.

What we found really is very similar to what came out today, and that is, really, that 95 percent of the industry leaders and regulatory officials agree that contaminated hands can contaminate food. So if your solution here is do contaminated hands contaminate food, there's already agreement on that. What the industry is really looking for is for you to take more of a leadership position, I think, in this.

We observed in our review of security tapes, for example, that the hand wash opportunities or glove change opportunities were about 134 opportunities per shift, and nowhere along the lines have we talked about those kinds of numbers for either hand washing or glove changes. So this really suggests that secondary barriers and some pharmaceutical applications are really needed in this environment.

In observation, the preparation areas behind the line are quite complex, as Frank had mentioned earlier, and this agrees with others, and we find it no wonder when we convened our focus groups that they've said there's no time for hand washing. The reason why there's no time for hand washing is a lot of it is because the sink isn't immediately accessible. The denominator of one sink per food facility is just simply too low. The denominator needs to be raised so that there is at least one hand wash sink in every preparation area, including the bread stations, and at least one about every 20 feet in long preparation lines. Hands-free washing speeds that process.

We also found that people said that there's no time to get water at the right temperature, that the 110-degree water temperature in the food code is simply too hot, and that it results in redness and soreness in some people, and that we agree with CDC that a comfortable wash is important and that the food code change really needs to be that the minimum wash temperature needs to be 90 degrees, not at 110 degrees, because of some of the sensitivities in some of the food handlers.

Then we found that people said there was no time to scrub for 20 seconds, just like you, Jim, and we were pleased to see that Jack's study showed there was no

significant difference between a ten-second wash and a three-minute wash. So we thought that we would recommend that since time is of the utmost necessity here, that ten seconds would be appropriate.

Then we talked about no time for education and training because of turnover. The industry turnover rate is 133 percent per year. Our NIHA survey demonstrated that the most effective ways to improve hand washing frequency were closer monitoring, more convenient sink location, and more interactive training, and that the least effective method seemed to be fines, making regulations more well known, increased health authority visits, and reminder posters. So we think this points to a regulatory approach requiring industry to train their employees and to health authorities to observe the behavior changes as part of their inspection visits.

And then finally, we found that people were saying there's no time to keep the hand wash sink clean, and as Dr. Schaffner and his colleagues found at the Food Risk Analysis Initiative, touching spigots during hand washing results in the same transfer rate as handling ready-to-eat food with contaminated hands. Where the transfer rate is greatest is where the sinks are shared, and where the biggest impact is is that uncontaminated hands clearly pick up contamination

from the faucets. So we think that whether you're using knee pedals, foot pedals, elbow pedals, electronic delivery, touch-free method in hand wash sink in terms of engineering and design is needed.

We want to thank you for allowing us to present this material, and if we can be of any assistance, we'd be glad to help. Thank you.

DR. POTTER: Are there questions for Mr. Budd? Yes, David?

DR. ACHESON: You said there were 134 opportunities per shift. Is that per person?

MR. BUDD: Yes, behind the line.

DR. ACHESON: And how many times did they avail themselves of the opportunities?

MR. BUDD: About 15.

DR. ACHESON: Fifteen?

MR. BUDD: Fifteen, 25, in that area. It depends on the individual.

DR. POTTER: Other questions?

[No response.]

DR. POTTER: All right. In that case, I'd like to thank the public participants and the presenters today. We're ready to close up shop, then, for today and be ready tomorrow for a committee discussion on the questions. I'd

like to leave you with those questions so that you can mull them over tonight and then I'll repeat them again because I enjoy that sort of thing in the morning.

[Laughter.]

DR. POTTER: The first question is, do you believe that bare-hand contact with ready-to-eat foods is a contributing factor in the transmission of foodborne illness? If so, can the transmission of foodborne illness via bare-hand contact with ready-to-eat foods be interrupted by any means? And if you believe it's possible to interrupt transmission, which single or combination of excluding ill food workers, hand washing and personal sanitation regimes, and prohibition of bare-hand contact with ready-to-eat foods is likely to provide the maximum public health benefit in terms of reducing the incidence of foodborne illness?

DR. O'BRIEN: Would it be possible to get a copy of those, to pass around the questions. Every word has to be memorized--

DR. POTTER: Yes. LeeAnne tells me that I'm supposed to behave and give you a clean copy in the morning.

DR. O'BRIEN: Thank you.

CHAIRPERSON WACHSMUTH: I said no housekeeping, but one piece you might want to hear is that we will be in this room the remainder of the meeting, so you can leave

things other than computers and such. That's probably not wise. But you can leave your reading materials. That's all. We're adjourned.

[Whereupon, at 4:33 p.m., the proceedings were adjourned, to reconvene at 8:00 a.m. on Wednesday, September 22, 1999.]

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