

1 distribution systems and geographical areas as they
2 exist throughout the supply chain.

3 Practices that pose significant risk of
4 microbial contamination should be evaluated and
5 mitigation practices established to reduce them.
6 Responsible production, packing and handling
7 procedures based on guidance documents available to
8 the industry result in the vast majority or virtually
9 all tomatoes posing no risk to public health.

10 The focus needs to be on the relatively rare
11 occasions when microbial contamination occurs.
12 Currently, there are no mandatory programs for
13 microbial testing in place throughout the industry.
14 It is anticipated that the Florida program will be
15 risk-based and will include those that are
16 appropriately based on realistic risk assessments.

17 Issue number two, the establishment of
18 uniform science-based risk evaluations and mitigation
19 procedures and procedures throughout the entire supply
20 chain is essential to providing the safest food supply
21 system possible.

22 Nationally mandated and monitored regulation

1 presents the best opportunity for accomplishing the
2 goal of overall risk reduction. Such a program must
3 be developed best on the commodity specific systems
4 that implements risk-reducing procedures and
5 procedures that address legitimate food safety
6 concerns. The industry in both Florida and California
7 has begun this effort to develop functional GAPs and
8 BMPs for tomatoes.

9 Issue number three, tomatoes due to the
10 unique market structure of repacking and distribution
11 presents real challenges to the traceback process. I
12 think Jack will attest to that.

13 Rapid, accurate traceback is essential to
14 all interests and should be pursued aggressively.
15 Mandatory traceback capability is the only acceptable
16 solution to this issue.

17 Positive lot identification, "PLI,"
18 throughout the system that minimizes comingling must
19 become the requirement if traceback is to be used to
20 limit injury to the public and the industry. Rapid
21 use of this tool can begin to provide valuable
22 information on the specific route through which

1 microbial contamination occurs.

2 Issue number four, mandatory compliance to
3 GAPs and BMPs through a national program of regulation
4 and regulatory oversight can significantly enhance the
5 risk reduction provided by these practices.

6 The risk for fresh tomatoes will never go to
7 zero with current technology, but significant
8 reductions can be achieved with such an effort. Direct
9 marketing of small quantities of tomatoes poses a very
10 limited risk to public health.

11 Such activities could be carefully exempted
12 from portions of such regulations to avoid
13 unreasonable impacts provided significant
14 circumvention would not be encouraged. After all it
15 is fundamentally in the interest of all participants
16 in the industry to produce the safest tomatoes
17 possible.

18 In summary, the Florida tomato industry
19 along with other groups such as the California tomato
20 farmers are proceeding on a path to improve the
21 overall food safety environment for tomatoes and, for
22 the record, I would like to add the 10 high-priority

1 research needs from the Tomato Food Safety Research
2 Needs Workshop held here in College Park on February
3 21 and 22. I appreciate the cooperation and ongoing
4 discussions on tomato food safety with FDA and the
5 opportunity to express our thoughts on these issues.

6 Thank you.

7 (Applause.)

8 MR. GUZEWICH: Mr. Brown, thank you. This
9 is Jack Guzewich with FDA. I have one question, and
10 you will get tired of hearing it before the day is out
11 from me. In your estimation, are Florida tomato
12 growers understanding and implementing GAPs?

13 MR. BROWN: A very significant portion of
14 our Florida tomato production system, probably upward
15 to 80 percent or better, are currently and have been
16 for a number of years under third party audits for the
17 GAP process and procedure and are practicing those on
18 a routine daily basis.

19 Food safety and GAP regulation or GAP
20 compliance is something that just shouldn't take place
21 and, hopefully, doesn't ever take place in a situation
22 of a single audit. It's something that's got to be

1 fundamentally ingrained in the corporate psychic of
2 these companies. We are well on that way, and that's
3 why this industry is willing to step forward to a
4 mandatory program.

5 MS. LEWIS: This is Glenda Lewis with FDA.
6 Actually, I have two questions. You mentioned about
7 the mandatory program. What impact do you see for a
8 mandatory testing and sampling program in the
9 industry? Is the industry willing to accept that?

10 MR. BROWN: A mandatory testing and sampling
11 program? We're looking at a mandatory BMP/GMP program
12 with an audit process that would ensure that those
13 items are complied with.

14 We have not gotten down to the final
15 rendition of the program to the point to be able to
16 give matrices to specifically talk about this test of
17 water and that test of water.

18 While those are significant parts of that
19 process, the industry has committed to continuing
20 their forward progress in dealing with food safety
21 issue for tomatoes based on science and real risk.

22 MS. LEWIS: My second question, would you

1 expand a little on specific activities that you may
2 recommend for exemption if there is any national
3 program of regulation?

4 MR. BROWN: I believe in the regulation that
5 we are proposing in Florida, and again it's a proposal
6 to go forward ultimately to be, hopefully, enacted
7 into regulation by state government, we are exempting
8 direct sales from the grower to the consumer in
9 quantities of less than 50 pounds per individual sale.

10 That allows for roadside stands that are
11 growing and selling a limited number of tomatoes to a
12 roadside operation. It allows for a certain amount of
13 you-pick business that may exist around the country or
14 around in our state in some cases.

15 It also doesn't allow for significant
16 circumvention of the requirements that may be upon the
17 remaining portion of the industry to ensure that we
18 are doing absolutely all we know how to do to make the
19 tomato products that we are selling the safest
20 possible products.

21 MR. LANDA: This is Mike Landa. Just one
22 question, is there some process for certifying or in

1 effect certifying auditors?

2 MR. BROWN: We have in the proposed
3 regulation. Initially the proposal for the regulation
4 going forward will have the state government or state
5 agency doing the auditing.

6 There is a provision within our documents
7 to, after the creation of the audit, the creation of
8 the audit procedure through governmental enforcement,
9 a provision for third-party certification to the
10 standard audit, to the standard procedure that has
11 been established by a government regulatory audit.

12 MR. LANDA: Thank you.

13 Anyone else?

14 (No verbal response.)

15 MR. LANDA: Our next speaker is
16 Anthony Corbo from Food and Water Watch.

17 MR. CORBO: Thank you very much. My name is
18 Tony Corbo, and I'm a legislative representative for
19 Food and Water Watch, a nonprofit consumer
20 organization that was founded in November 2005 and is
21 based in Washington, D.C. I welcome this opportunity
22 to offer our comments on improving produce safety in

1 light of the recent national recalls.

2 At the outset, I want to reiterate the
3 points that Caroline Smith-DeWaal made earlier today,
4 that the Food and Drug Administration is an agency in
5 crisis.

6 There have been too many recalls involving
7 products under the Agency's jurisdiction in recent
8 years, and it's becoming clear that the Agency may
9 not have the authority and the necessary financial
10 resources to do its job to protect American consumers.

11 These recalls are undermining consumer
12 confidence in the Agency. The situation is becoming
13 especially critical on the food side of FDA. The word
14 "food" is the first noun in the Agency's name, yet it
15 seems that food safety has become the stepchild within
16 the Agency and within the overall food safety net in
17 the Federal Government.

18 Just consider some of these facts. FDA's
19 Center for Food Safety and Applied and Nutrition along
20 with FDA's Office of Regulatory Affairs are
21 responsible for regulating \$417 billion in domestic
22 food and \$49 billion in imported food that is produced

1 in some 126,400 domestic food establishments and
2 172,000 foreign establishments.

3 In the current fiscal year, CFSAN has been
4 given the meager staff of some 2,700 full-time
5 equivalent positions to police 80 percent of the
6 nation's food supply.

7 An FDA inspector is lucky to have visited a
8 plant on his or her beat once every five years. FDA
9 port inspectors are hard pressed to inspect even
10 1 percent of imported food. This situation is
11 reprehensible and requires immediate action to
12 correct.

13 Food and Water Watch believes that there is
14 need for national enforceable standards to regulate
15 fresh produce food safety. Simply issuing guidances
16 to industry is not going to instill confidence in
17 consumers that FDA is protecting the food safety.

18 FDA inspection personnel need to be able to
19 act when they find the food safety system failures
20 before the food enters into commerce. There are some
21 in the produce industry who are calling on FDA to
22 develop enforceable standards.

1 There are legislative initiatives in some
2 states -- for example, we have already heard in
3 California and in Florida -- to set up a regulatory
4 framework to govern food safety in the fresh produce
5 industry.

6 FDA needs to heed these calls for
7 regulation, begin the process to develop food safety
8 standards that can be enforced by the Agency
9 nationally.

10 Furthermore, if the Agency does not believe
11 that it has the authority to set up a regulatory
12 framework for produce, then it should seek legislative
13 authority to do so from the U.S. Congress.

14 Food and Water Watch is also concerned with
15 the public health consequences of concentrated animal
16 feeding operations, or "CAFOs." There has been a
17 growing trend in the nation to raise large numbers of
18 livestock in confined quarters.

19 The manure that is produced by the animals
20 in CAFOs can lead to polluted runoff, carrying
21 pathogens from these facilities that can impact nearby
22 produce fields.

1 I was surprised that there was so much
2 discussion about water and animal reservoirs of
3 pathogens and that EPA, the regulatory agency that
4 regulates some of these operations, was not invited to
5 participate in this conference.

6 We are especially concerned with the
7 ever-growing dairy cow population in the San Joaquin
8 Valley of California. There have been reports that an
9 additional 300,000 heads of cattle will be moving into
10 that area of California over the next few years.

11 Over 75 percent of the state's 1.7 million
12 head of dairy cows already are raised there. The
13 San Joaquin Valley is also a major center of fresh
14 fruit and produce production in the state whose
15 products are shipped around the world.

16 The EPA regulates CAFOs as part of its
17 responsibilities under the Clean Water Act. Just last
18 year, when it was forced to rewrite those regulations
19 due to a federal court decision, the EPA had the
20 opportunity to compel the operators of CAFOs to
21 install more stringent pollution controls to reduce
22 the levels of pathogens and discharges from these

1 farms, but it chose not to do so.

2 We strongly urge FDA, EPA, state and local
3 authorities to collaborate to develop reasonable
4 buffers between livestock farming operations and
5 produce fields to reduce the possibility of produce
6 contamination from CAFO pollution, and for strict
7 enforcement of the Clean Water Act as it applies to
8 CAFOs. With that action, there is recipe for major
9 ecological and food safety disasters in a state that
10 produces so much of our fresh produce.

11 Lastly, we would like to address the calls
12 by some in industry for the increased use of
13 irradiation to deal with foodborne pathogens. Food
14 and Water Watch opposes the use of food irradiation
15 because we believe that FDA still has not done enough
16 of its own research to determine whether the
17 technology is safe.

18 In the case of fresh produce, we believe
19 that the use of irradiation could cause degradation of
20 the product and raise palatability issues. We also
21 view irradiation as a potential "crutch" or "silver
22 bullet" that could be used by some in industry as a

1 substitute for good manufacturing and agricultural
2 practices.

3 Consumers don't want to eat poop whether it
4 is treated or untreated. We should encourage produce
5 farmers and processing houses to maintain sanitary
6 practices without the need for invasive technologies.

7 Thank you very much.

8 (Applause.)

9 MR. LANDA: Any questions?

10 Linda?

11 (No verbal response.)

12 MR. LANDA: Thank you.

13 We're going to go a little out of order here
14 due to some travel schedules, so our next speaker will
15 be Rayne Thompson from the California Farm Bureau
16 Federation.

17 MS. THOMPSON: Thank you very much. I would
18 like to get back to California tonight, so Charles has
19 given me a pass.

20 My name is Rayne Thompson with the
21 California Farm Bureau Federation. I am the director
22 of international trade and plant health of the

1 California Farm Bureau Federation. We represent
2 91,500 farmers and ranchers in California that grow
3 350 different commodities. Consumers, growers,
4 retailers, regulators and others are demanding change
5 in food safety.

6 Our main goal is providing consumers with
7 healthy, California-grown products. The spinach
8 incident underscored the importance of handlers and
9 farmers creating a program that will establish best
10 management practices and that can be uniformly applied
11 and verified.

12 Through the recently accepted California
13 Marketing Agreement, we have created this program.
14 This program allows USDA or its designee to verify
15 good agricultural practices. We believe USDA or its
16 designee is the best venue because it has both the
17 experience, oversight, and resources to implement an
18 effective verification program.

19 As Mr. Nassif pointed out before, we have
20 shown great success in our marketing agreement in
21 terms of we have 98 percent of the volume of leafy
22 greens that goes out of the state of California

1 covered underneath that program.

2 These GAPs focus on main areas on the farm:
3 water, wildlife, soil amendments, and adjacent land
4 use. We have based our good agricultural practice
5 metrics based on current science that leads us to
6 believe implementing these programs will reduce food
7 safety risks.

8 These GAPs give growers indicators on
9 potential risk areas and they give them mitigation
10 action that they have to do. If you want me to go
11 further on that, I'm willing to with further
12 questions.

13 Basically, they have to document all of
14 these activities that they have done through water
15 testing, adjacent land uses and then they are audited
16 by USDA, which I currently think that they have
17 designated CDFA to be the auditor in that program.

18 We are looking at, the California Farm
19 Bureau itself is looking at developing training
20 programs that can be applied in the farm for primarily
21 the farm worker to understand what this means to them
22 and what practices they have to implement themselves.

1 One thing that we do have to consider is the
2 impact this has on small to medium growers around the
3 country as well as California. We have to look at
4 programs that offset the costs for complying with
5 these food safety programs.

6 One of the major benefits with this program
7 is that we will have more on-farm data available to
8 us, so we can better define practices down the road.
9 One of the main components that was brought up this
10 morning and that we have found with the spinach
11 outbreak is that there are so many questions with so
12 little information.

13 Research is obviously a main component. We
14 ask both the public, consumers, FDA, and the industry
15 to invest their funds in further research. PMA has
16 done a great job of stepping forward with \$2 million.

17 We see the whole entire continuum. Farmers
18 have focused on on-the-farm practices, but we also
19 realize that we need to be looking at transportation,
20 processing, and once you get into your kitchens and
21 homes.

22 A federal marketing order is an option.

1 However, we want you to look at a program that is
2 specific to the commodity as well as the regional
3 diversity and risks that are included in that.

4 Any success of a program should take into
5 account the commodity food safety risks, the region,
6 and growing cultural practices and processing
7 practices.

8 In regards to how the Food and Drug
9 Administration plays an important role to all of this,
10 the Taco Bell incident that occurred underscores the
11 fact that FDA plays an important role in educating
12 consumers and providing the public with being a
13 reliable source for information.

14 The media frenzy around that incident
15 quickly jumped to conclusions. Unfortunately, they
16 did not hear the message loud and clear from the Food
17 and Drug Administration.

18 I have to at this point commend the
19 California Department of Health Services. I was on
20 several of the calls that they had with the media.
21 They specifically explained to the media that these
22 were just preliminary indications regarding onions,

1 and that they were still looking at other commodities.

2 Unfortunately, the media did not pay
3 attention to that. We believe that FDA needs to play
4 a stronger role in stressing to the media the facts
5 and the information.

6 We look forward to working further with you
7 on this issue. We look forward to providing consumers
8 with a healthy product both in California, in the
9 country, and around the world.

10 Thank you very much.

11 (Applause.)

12 MR. GUZEWICH: This is Jack Guzewich at FDA.
13 Thank you for that presentation. Since you represent
14 so many farms in California, I feel it's appropriate
15 to ask you the same question I've been asking others.
16 Do you think the growers in California understand
17 about agricultural practices? Do you think they are
18 implementing them at this time?

19 The big question we are facing here is, do
20 we need more standards or is this just a question of
21 the standards we already have not being followed?
22 That's the question we're trying to understand.

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1 MS. THOMPSON: Right. You know, we got that
2 question at the very beginning of the outbreak because
3 that was the main question is, does everyone
4 understand the rules. I think with the marketing
5 agreement it really enforces the rules.

6 I will be honest with you, the marketing
7 agreement and auditing process does not go into
8 effect, I think the first audits are going to happen
9 after April 23.

10 Today, I would say unfortunately what we are
11 seeing from a lot of buyers are different ag
12 practices. I think they are focusing on those main
13 areas, but they are slightly different.

14 After the 23d, I think you will see that you
15 will have more people going by the rules. I think
16 they are implementing them. Is everyone doing the
17 exact same thing today? I would say there is some
18 question as to that.

19 MR. BACA: This is Joe Baca with FDA. You
20 mentioned the marketing agreement. What are the
21 consequences to the growers of not complying with the
22 market agreement?

1 MS. THOMPSON: How the marketing agreement
2 works is it is actually focused on the handler signing
3 up and the requirement of being a signatory to the
4 handler, you can only buy from growers that adhere to
5 good ag practices, and so they have to be audited to
6 those good ag practices.

7 You cannot buy from a grower that is not
8 adhering to those. If they fail to adhere to it, then
9 buyers will not buy from them as well. You basically
10 are out of the supply chain.

11 MR. BACA: Thank you.

12 MR. LANDA: Any other questions?

13 MS. LEWIS: This is Glenda Lewis with FDA.
14 Does transportation play a role in the marketing
15 agreement. I know you mentioned the suppliers and the
16 handlers. Is that aspect also being considered as a
17 part of that?

18 MS. THOMPSON: It is. What we have done
19 right now is we have primarily focused, you know,
20 we've had to bite this off in chunks. You can't do
21 everything at once, and we've moved rather quickly in
22 the amount of time that we have.

1 The first chunk we bit off was on farm
2 practices, and the next chunk will be processing and
3 transportation. That is why we really encourage FDA
4 to play a strong role in reminding those industries
5 that they also play an important part of this. Just
6 because you've handled one does not mean that you've
7 handled all. We do need your help in reminding them
8 that they also play an important role in this.

9 MR. LANDA: Anyone else?

10 (No verbal response.)

11 MR. LANDA: Thank you.

12 MS. THOMPSON: Thank you.

13 MR. LANDA: It is now just a little after
14 3:00. We would like to take a short break and
15 reconvene at 3:15, please.

16 Thank you.

17 (Recess taken.)

18 MR. LANDA: Would everyone take their seats,
19 please. Our next speaker is G. Michael McCartney of
20 QLM Consulting.

21 (No verbal response.)

22 MR. LANDA: I stand corrected. Our next

1 speaker is Alfred Murray from the New Jersey
2 Department of Agriculture.

3 (No verbal response.)

4 MR. LANDA: In the interest of moving things
5 along, we will try to catch up with other people,
6 assuming they are still here, but our next speaker is
7 going to be Joe Rajkovacz, Owner-Operator Independent
8 Drivers Association, Inc.

9 MR. RAJKOVACZ: Good afternoon. My name is
10 Joe Rajkovacz, regulatory affairs specialist for the
11 Owner-Operator Independent Drivers Association.
12 Additionally, until a year ago, I spent over two
13 decades hauling produce out of California back into
14 Wisconsin and Minnesota.

15 The association appreciates the opportunity
16 to speak about conditions within the fresh produce
17 industry that directly affect the safety of the
18 products shipped for human consumption.

19 Our more than 151,000 members operate over
20 240,000 trucks nationwide. An integral part to the
21 supply chain is transportation. Small business
22 truckers and their drives are the overwhelmingly

1 dominant providers of fresh produce transportation.

2 Focusing fresh produce safety narrowly on
3 E. coli contamination clearly misses other significant
4 entry points of foodborne pathogens that intuitively
5 are implicated in fresh produce safety.

6 The agricultural industry attempt to thwart
7 significant regulatory oversight through voluntary
8 best practice guidelines related to food safety should
9 be viewed with skepticism.

10 Best practices have been well known for many
11 years, but economic considerations have trumped
12 meaningful implementation. An exposé carried by
13 Dateline NBC on March 25 exposed poor conditions at a
14 wholesale produce market in Los Angeles. It was not
15 shocking to most produce truckers. We have been
16 forced to live with filthy conditions like that for
17 decades.

18 OOIDA had described similar conditions in
19 our comments opposing an industry-push marketing
20 agreement with the California Department of Food and
21 Agriculture. We are not fans of the marketing
22 agreement, along with some others, primarily because

1 of its lack of inclusion in it and lack of
2 transparency.

3 Unsanitary and unsafe practices related to
4 handling and shipping fresh produce is not limited to
5 California. It is a nationwide problem. Significant
6 numbers of shipping and receiving facilities around
7 the country could have just as easily have been
8 highlighted by reporters and hidden cameras.

9 The lack of sanitary bathroom facilities and
10 hygienic conditions in which to work is all too common
11 in the fresh produce industry. Produce truckers are
12 exposed regularly to bathrooms lacking running water,
13 soap, and towels.

14 Portable toilet facilities that are only
15 given scant attention are common. These are often so
16 filthy we drivers prefer to stand beside trucks and
17 relieve ourselves.

18 Even when modern, clean facilities are
19 available, we will be denied their use because of
20 deeply seated animosity against drivers. Many
21 shippers and receivers within the fresh produce
22 industry exhibit a callous disregard for cleanliness

1 and sanitation procedures.

2 The idea of maintaining a clean and sterile
3 environment to minimize microbial contamination is
4 given short shrift when compared to economic
5 considerations.

6 Since much fresh produce is intended to be
7 eaten in its raw form, minimizing human handling
8 should be an obvious strategy to minimize potential
9 microbial contamination associated with too much human
10 contact.

11 A common practice within the produce
12 industry that is counterintuitive to minimizing
13 excessive human contact places the truck driver as
14 responsible for manually unloading and literally
15 touching every box of produce coming off a trailer.

16 We call it "fingerprinting a load." If the
17 driver doesn't do it, he hires a surrogate that we
18 call a "lumper." This practice is purely economic in
19 origin, that transfers warehouse labor costs to the
20 trucker and compromises food safety.

21 The use of recycled pallets wet or stained
22 with animal blood, residue of previous chemical

1 shipments, and bug infestations is common. Also,
2 loading of clearly unsanitary trailers, improper
3 loading of refrigerated trailers in violation of
4 manufacturer specifications happens frequently.

5 Last years outbreak of E. coli in spinach
6 and the subsequent voluntary recall left many small
7 business produce truckers with the financial
8 responsibility to find dumping facilities for rejected
9 product.

10 It is a common industry practice to evade
11 financial responsibility by leaving truckers holding
12 the bag when dealing with recalled or rejected
13 product. We are their dumping ground.

14 The lack of any mandatory assigned
15 responsibility by the FDA during a recall indirectly
16 allows rejected rotted, contaminated produce to enter
17 the food supply chain.

18 Produce truckers financial losses are under
19 economic pressure to find the quickest dumping
20 solution. Dumping product at the back of a truck stop
21 or along a highway is common. Produce truckers have
22 found that giving produce away to the general public

1 is an effective method to extricate ourselves from
2 this Pandora's box. In a post-911 world, this is a
3 recipe for disaster that will never contain any
4 inadvertent or purposeful contamination of fresh
5 produce.

6 The produce industry has exhibited a
7 historical lack of responsibility when dealing with
8 the men and women charged with safely and efficiently
9 hauling America's fresh produce. It is hard to
10 imagine a solution to fresh produce safety without
11 intervention at the highest level of government.

12 Thank you.

13 (Applause.)

14 MR. GUZEWICH: Thank you for that
15 presentation. This is Jack Guzewich with FDA. I have
16 one question. We hear, not infrequently, anecdotal
17 reports that truckers leave the West Coast and for
18 economic reasons turn off the refrigeration unit on a
19 truck until an hour or a half a day before they arrive
20 at the destination and then they turn it back on. Can
21 you comment on that allegation?

22 MR. RAJKOVACZ: Yeah. I read that in the

1 "San José Mercury News" this past year, and it was an
2 individual from the California industry that said
3 that. It is an outrageous statement.

4 I am the one who is financially responsible
5 for any claims related to that load based on
6 temperature. They put temperature recorders in these
7 loads, and if that equipment is not maintained at the
8 right temperature, that load is going to get kicked.
9 I'm going to be the one that pays the claim.

10 MR. ZINK: Don Zink with FDA. In my time in
11 industry, I think I see much of what you were talking
12 about. I don't have a feel for how prevalent it is,
13 but I am familiar with loads that got left by the side
14 of the road, and these things.

15 You say you're often left holding the bag
16 with recalled product. Could you describe a scenario
17 whereby a trucker, essentially, gets stuck with no
18 place to go with a load of rejected product?

19 MR. RAJKOVACZ: One of the reasons that this
20 happens is because the trucker -- in fresh produce it
21 is almost always the buyer who pays the freight. The
22 trucker has a contractual relationship with the buyer

1 of the produce.

2 In the case of last fall, when the spinach
3 was recalled, the buyers put the stuff back on our
4 members' trucks. They have no contractual
5 relationship with the shipper, so they ended up
6 holding the bag, unless they of course got a lawyer
7 and sued the shipper for reimbursement for the cost.

8 MR. ZINK: You show up at a destination with
9 a load, and nobody will let you unload it?

10 MR. RAJKOVACZ: In the case of one of our
11 members, he was not allowed to unload an entire load
12 of spinach. He had to haul it from Atlanta to
13 Memphis. We highlighted in our magazine, "Land Line."

14 That was the first place he could find a
15 dump that would take it, and he had to manually unload
16 the entire trailer into the dump. All he was
17 reimbursed was \$200 for the dump tipping fee and none
18 of his costs associated with transporting it from
19 Atlanta to Memphis.

20 MS. LEWIS: This is Glenda Lewis, FDA. What
21 mechanisms do you have for maintaining the temperature
22 control? How is that handled on the trucks?

1 MR. RAJKOVACZ: If I'm hearing you
2 correctly, you are wondering how the temperature is
3 maintained in transit?

4 MS. LEWIS: Yes. What mechanisms are you
5 currently using to assure that?

6 MR. RAJKOVACZ: Well, reefer units,
7 obviously you turn it on and you set the temperature.
8 Many receivers, the buyers of freight, will demand to
9 have temperature recorders placed on the freight that
10 monitors in-transit temperature.

11 Additionally, many new refrigeration units
12 have built into them temperature recording equipment
13 that, quite frankly, we truckers use as insurance
14 against receivers who didn't require a temperature
15 recorder being placed on the load.

16 In all the years that I hauled produce out
17 of California, I would ask for a temperature recorder.
18 But if the buyer hadn't requested it, I was refused it
19 to be put on because it cost 25 bucks.

20 MR. LANDA: Thank you very much.

21 MR. RAJKOVACZ: You bet.

22 MR. LANDA: Our next speaker is

1 G. Michael McCartney, QLM Consulting.

2 (No verbal response.)

3 MR. LANDA: Then, I guess our next speaker
4 is Alfred Murray, New Jersey Department of
5 Agriculture.

6 MR. MURRAY: Good afternoon everybody. My
7 name is Al Murray. I serve as the assistant secretary
8 of agriculture for the New Jersey Department of
9 Agriculture.

10 I am here on behalf of Secretary Charles
11 Kuperas as well as members of the New Jersey
12 agricultural industry. We are here to present New
13 Jersey's views on your important mission, to help
14 enhance the safety of our nation's food supply.

15 Last September, New Jersey's farmers,
16 particularly our spinach farmers, faced a crisis. As
17 the fall harvest approached, the Food and Drug
18 Administration advised consumers should not eat fresh
19 or bagged spinach or mixed salad greens containing
20 fresh spinach due to contamination by the deadly
21 E. coli. We all know that.

22 Timing couldn't have been worse for our

1 farmers. The final irony for New Jersey came with the
2 subsequent announcement that the contamination was
3 limited to an area 3,000 miles away on the West Coast.

4 This interconnectedness of the produce
5 industry is primarily the reason why efforts to
6 improve the safety of produce growing, shipping,
7 processing, retailing must be uniform, appropriate,
8 and attainable across the nation.

9 Our produce growers, shippers, processors,
10 and retailers must act in a unified, standardized way
11 to ensure consumer confidence and to prevent fresh
12 produce, which we all consider a part of the healthy
13 diet, from being avoided by our nation's consumers.

14 Fruits and vegetables in New Jersey account
15 for \$262 million of our farm gate receipts annually.
16 Nationally, New Jersey ranks second in the production
17 of blueberries, third in the production of peaches,
18 and we are among the top ten states in the production
19 of bell peppers, cucumbers, head lettuce, sweet corn,
20 and spinach. Clearly, we have a large stake in this
21 issue.

22 The cornerstone we believe in improving

1 produce safety is, in our view, third-party audits for
2 the growers. The three key tenets of this effort must
3 be using the USDA third-party audit protocols,
4 ensuring the cost of passing the audits does not
5 exceed the farmer's reach, and providing enough time
6 to implement the standards.

7 We suggest that the FDA and the USDA work
8 together to devise a system that recognizes the
9 differences in farm operation sizes, the unique
10 qualities and methods for growing and harvesting
11 fruits and vegetables, and differences in irrigation
12 techniques.

13 Although audits will differ based on these
14 variations, the goals of these audits should remain
15 the same. A one-size-fits-all approach we think would
16 be misguided, but a one-goal-fits-all is central for
17 an effective auditing system.

18 New Jersey's recently formed Produce Safety
19 Task Force has learned that growers and brokers are
20 frustrated when produce buyers insist upon third-party
21 audits performed by a private company specified by the
22 buyer which adds an additional cost burden to our

1 growers.

2 With a national produce safety standard
3 devised jointly among the FDA and the USDA and
4 administered by the USDA, state departments of
5 agriculture could work with our land-grant
6 institutions to ensure that all growers seeking
7 third-party auditing could afford an audit acceptable
8 to buyers.

9 The third key element is ensuring that all
10 producers have enough time to meet the requirements of
11 third-party audit certification. Infrastructural
12 improvements, operational changes, employee training,
13 and recordkeeping updates won't be accomplished by all
14 sizes of operations in the same amount of time.

15 We believe national standards and
16 third-party auditing cannot accomplish the goals of
17 uniform food safety unless the first level of
18 production, farmers, buy into the program.

19 New Jersey has mobilized quickly in this
20 effort. To date, our Department of Agriculture along
21 with Rutgers University has trained more than 700
22 farmers in food safety preparing them to go further in

1 the auditing process.

2 Also, not all produce commodities require
3 the same safety measures. Our Produce Safety Task
4 Force recommends variations in the audits divided into
5 three classes: tree and small fruit crops, on-ground
6 crops, and underground crops. Implementation should
7 have three components: education, cost-share
8 assistance, and research.

9 In education, any effective program must
10 include a strong educational component. This should
11 and could include information on how farmers can work
12 together to accomplish food safety goals.

13 It should include food safety training for
14 farm employees and managers, education on implementing
15 the auditing process, and instruction in maintaining
16 clear and understandable production records.

17 Cost-share assistance, we respectfully
18 request that the Federal Government provide cost-share
19 assistance to farmers whose financial position may
20 stand in the way of achieving timely third-party audit
21 certification. This will facilitate wider food safety
22 coverage throughout the system.

1 The need for research, as food safety
2 technology advances, research is needed to enhance
3 audit protocols and standards. Any effective program
4 must have research components that include the
5 following: water quality and testing should be
6 consistent and should be cost effective.

7 Produce sampling in the field must employ
8 uniform and attainable methods. Traceback records,
9 which I think everybody has been talking about today,
10 they have got to be clear and understandable.

11 In conclusion, you are faced with a great
12 challenge to move the food safety of our economy to
13 greater heights without negatively impacting the farm
14 families and the small businesses who grow, ship,
15 process, and sell this food.

16 We believe that you must embrace the USDA
17 standards with variations of protocols for different
18 classes of produce, allow adequate time to implement
19 these safeguards, and provide cost sharing and
20 research to help the participants in the market chain
21 obtain these goals.

22 The job ahead is daunting, but we believe it

1 can be accomplished with the help of the FDA, USDA,
2 state departments of agriculture, land-grant
3 universities, and all those in the fresh produce
4 marketing chain. We enthusiastically offer the help
5 of the New Jersey Produce Safety Task Force in your
6 efforts.

7 We believe that working together nationally
8 as we have begun to do so in New Jersey along with all
9 the appropriate agencies and segments of the market
10 chain we can achieve produce safety standards to meet
11 the high expectations of our nation's consumers.

12 Thank you.

13 (Applause.)

14 MR. GUZEWICH: This is Jack Guzewich with
15 FDA. Thank you for that presentation. Just one
16 question. On these third-party auditors, we've heard
17 this question today earlier as well, how do we assure
18 uniformity among these auditors so that it applies
19 equally across areas?

20 MR. MURRAY: That's something that we are
21 calling for. We would hope that all third-party
22 auditors, whether they are private companies, whether

1 they be USDA certified, which in New Jersey our state
2 employees that are inspectors that are part of the
3 third-party auditing they are certified under the
4 USDA. They would all be uniform. The standard of a
5 farm passing would be at a rate that would be uniform
6 across the board.

7 MR. GUZEWICH: How do we get there?

8 MR. MURRAY: That is what we are hoping you
9 guys can show us.

10 (General laughter.)

11 DR. SOLOMON: This is Steve Solomon.

12 You are talking about the need for cost
13 sharing. Do you have some estimates what the costs
14 are for third-party audits?

15 MR. MURRAY: That depends also, if a buyer
16 requires a farmer to use a private company, we have
17 heard estimates of \$1,500 or \$1,600. Again,
18 New Jersey's farms are a lot smaller than a lot of
19 people that are dealing. A USDA audit provided by our
20 inspectors can cost a farmer about \$500 or so, so
21 there is this cost savings if they go with the
22 USDA-certified audit.

1 The problem is a lot of buyers don't request
2 that. They request an audit from a private company.
3 We feel that that's unfair to the farmers who don't
4 have a say in who they can choose for this audit.

5 That, again, is why we are calling for a
6 standardized, across-the-board "This is the protocol
7 you need to follow." Regardless of who does the
8 audit, that's the one they would have to meet.

9 MS. LEWIS: This is Glenda Lewis with FDA.
10 In a world where money is not an issue and neither
11 staff resources, you mentioned the USDA third-party
12 audit system that is in place, is there any opposition
13 to FDA doing the audit system, if we had the resources
14 to do that? Why did you specifically pick the USDA
15 audit or another third party?

16 MR. MURRAY: Well, the USDA has the
17 established program. As a source of pride on
18 New Jersey, we were the first state to actually be
19 certified for our state inspectors to be under the
20 USDA Program. I don't think the FDA has a
21 certification program.

22 MS. LEWIS: We do not. I just wanted to

1 clarify why specifically that one or any third party.

2 MR. MURRAY: I don't think it would matter
3 to New Jersey who does it. I know that our produce
4 inspectors are cross-trained to be third-party audit
5 certified. The fact that there are eyes and ears on
6 the ground, particularly on the farms and processing
7 and throughout the marketing chain in New Jersey, it
8 makes for a good fit.

9 MR. LANDA: Thank you.

10 Our next speaker is Greg, forgive this
11 pronunciation, Drouillard (pronouncing "dru-yard"),
12 from Sunkist Growers.

13 (PowerPoint presentation is in progress.)

14 MR. DROUILLARD: Good afternoon. My name is
15 Greg Drouillard (pronouncing "dru-lard"). I am the
16 director of laser technologies at Sunkist Growers, and
17 I want to discuss natural-light labeling, which
18 happens to be a solution for this traceback problem
19 that we are having right at the moment.

20 There is an inconsistency between where it
21 comes out of the field and where it gets into the
22 carton and from the carton, comingling. We have a

1 solution to this problem. In particular, it has
2 positive implications for food safety and also the
3 Bioterrorism Act.

4 Essentially, the natural-light labeling
5 system concentrates a beam of light which is precisely
6 controlled to remove the pigment from the epidural
7 layer of your produce. It does not penetrate. It
8 only removes and is only accurate to the pigment.
9 That contrast is what you see as a label.

10 Essentially, sunlight grows your produce. We use
11 light to make the label, so it's a non-contact system.

12 The premise behind the development of a
13 natural-light labeling system was to provide the food
14 industry and the consumer with an alternative to
15 adhesive labels for food labeling. Of the many
16 advantages that the NLL system has offer, the most
17 significant is in the area of enhanced food safety
18 through traceability.

19 The five most important elements of an
20 effective traceability system are individual product
21 identification certification. It's permanent; it's
22 nontransferable. For example, nontransferable in

1 regards to a label in through a packing line, when it
2 gets labeled, that label can transfer to another
3 product throughout the system, somewhere in the
4 system, or it can come off altogether and a label of
5 some nonconsequence could get on a piece of product
6 and you could identify it incorrectly.

7 Another is a unique identification. You
8 would produce that unique traceability code, that
9 right now is being implemented from the grower level
10 and the carton level, you can transfer this code all
11 the way through.

12 The system is capable of also storing this
13 information for recordkeeping, so you can have
14 instantaneous tracking. If you have a problem, you
15 can quickly get onto the system via the Internet or
16 through any electronic measures and find out where
17 that piece of product came from.

18 Even if that product was separated from the
19 original carton it came from, it's easy enough to
20 actually put in the identifier and find out where it
21 came from, so it's not a problem if it's not with the
22 original carton it came with.

1 The next is tamper-proof. "Tamper-proof"
2 essentially means that in order to change this product
3 or change the identifier you would have to damage the
4 product in the first place. The tamper-proof method
5 is essentially damaging your product, if you try to
6 remove the code to hide what you're trying to do.

7 The natural-light labeling system uses no
8 consumables such as glue, plastic, paper, or ink to
9 create the label. The natural labeling system uses
10 light to label the produce.

11 This system can print virtually anything,
12 product and variety certification, organic or
13 inorganic, PLU numbers, country of origin, and
14 traceability information.

15 With respect to country of origin labeling,
16 essentially the packer has to inventory all these
17 labels. If he brings in produce from the outside,
18 from another country, he has to have labels with that
19 country's origin.

20 In fact, it is not a regulation at this
21 time, but it was a cost, a significant cost, which may
22 cause delay of the Food Labeling Act for

1 country-of-origin labeling.

2 This method you can instantaneously change
3 what country it came from. If you had a lot, for
4 example, a load of product that came from a different
5 country, then typically you would have to wait until
6 you get many loads to do this.

7 You could easily run that load as it came in
8 and then switch right back to a domestic load. It is
9 not a problem with this system. You could do so
10 without having to deal with volume storing or peeling
11 or maintaining or cleaning adhesive labels ever again.

12 A "PLU code," most of you are probably aware
13 of a PLU code. It's the "price lookup code." It's
14 the typical information that the retailer uses to
15 identify that piece of product. That piece of product
16 can be by weight or by quantity.

17 It's just a matter of what that code means
18 when they assign it at the retail level, even though
19 it has been assigned already, what the product
20 identification is.

21 In particular, when we speak about
22 "inorganic" and "organic" produce, you have an

1 appended "eight" or "genetic," and I didn't mention
2 this, "genetically engineered." You can actually do
3 that immediately without having to order more labels.
4 Also, the "nine" means "organically grown."

5 This is an example of a plum with the
6 natural-light labeling label on it. Features of it:
7 it eliminates the high-cost associated with adhesive
8 labels. It eliminates consumer complaints of adhesive
9 labels. There is no waste byproducts.

10 Very little energy consumption, it is a very
11 low-energy system. It is a green product favorable to
12 the environment because there is no consumable. There
13 is no waste product either, no tape or anything of
14 that nature. Traceability we mentioned; and no
15 consumables to label the produce, again.

16 We mentioned operational maintenance cost.
17 Typically, it costs manhours to maintain the labeling
18 system, to change out the cartridges, and so on, and
19 clean the equipment afterwards.

20 You don't have this with this system. This
21 system has been designed to last 10 years without any
22 significant overhaul. If, for example, its 10-year

1 lifespan has ended, it is easy to maintain and to
2 upgrade it for a very insignificant amount of money.

3 Your cost of ownership has gone down
4 immensely. You have no overhead associated
5 significantly with the system, other than the cost of
6 the machine when you purchase it or lease it at the
7 beginning.

8 You also only require one head per lane. I
9 won't go into great detail with that. Essentially, it
10 can coat on the fly. If you had 10 different pieces
11 of product and 10 different PLU numbers running at
12 10 a second, it will label those all individually.

13 Again, packers don't have to deal with
14 inventory overhead. It does not affect shelf life.
15 It is capable of marking produce that previously
16 adhesive labels couldn't such as cucumbers, for
17 example, potatoes, individual potatoes, if required.

18 It can also, of course, date and time stamp
19 the product lot code, batch code. You can put
20 virtually anything you would like on a piece of
21 produce.

22 I'm running out of time, so I'm going to

1 pass this. Again, the advantages are traceability and
2 also it prevents counterfeiting. As Sunkist is aware
3 and everybody is aware, there is significant
4 counterfeiting that can take place outside the U.S.
5 This inhibits that because you have an identification
6 code. You can put that on there, that you can certify
7 that that's your product, and it hasn't been changed.

8 At this time we also have 56 countries from
9 around the world accepting this technology, but also
10 they import into the U.S. At this time we also have a
11 food additive petition that is presently in the FDA in
12 which we are putting through -- well, we are waiting
13 for acceptance so we can go ahead with this product.

14 Again, here is another example of
15 natural-light labeling. This has the date. Here is a
16 green pepper. The last was a tomato. There is an
17 onion, onion skins, and a cucumber, an avocado, an
18 apple, and that's it.

19 Thank you.

20 (Applause.)

21 MR. LANDA: Don Zink with Food and Drug.

22 Two questions, you call this "natural light." What

1 exactly do you mean by "natural light"? Is this very
2 intense-focused white light? Is it a laser light,
3 et cetera?

4 My second question is, what do you think the
5 typical first-year cost would be for a packing house
6 to implement this, say, a tomato packing house to
7 implement this?

8 MR. DROUILLARD: Okay. To address the first
9 question, natural light, essentially the light that we
10 use, which is a concentrated beam of light, it has a
11 specific wavelength, only one wavelength. It is
12 10.6 micrometers. That is an infrared labeling.

13 Daily we are absorbing infrared. In fact,
14 we are absorbing it in this room right now from the
15 light. The infrared light that you are receiving now
16 ranges anywhere from near- to far-infrared.

17 Essentially, it is what we deal with every
18 day. In this particular instance, we are using very,
19 very low energy on the order of .675 watts of energy
20 in order to produce this label.

21 To address the cost, the cost issue,
22 typically we talk about the return on your investment.

1 It's hard to nail that down, but I will try to give
2 you an idea.

3 A typical packing house that has eight lanes
4 of product and they may have one to three banks of
5 labels will go through about \$200,000 to \$300,000
6 worth of labels a year, not including the inventory
7 carryover that they have to maintain. They have to
8 maintain that in a specified room at a temperature so
9 the labels don't lose their ability to adhere.

10 The other problem that they have is
11 maintaining them. You have to have someone always
12 watching over the reels and clogging and such and then
13 the cleanup afterwards.

14 Trying to explain this, if you have this
15 particular house, the return on the investment and the
16 dollars that we have seen in that one example, they
17 would see an immediate return somewhere in the order
18 of \$100,000 to \$280,000, a return of not a loss but of
19 a gain by going to this system.

20 If you had a smaller system, which would be
21 a four-lane system, it could take anywhere up to two
22 years to reclaim the cost. But as we are preparing

1 the system, you can lease the system, which you can
2 realize a return immediately.

3 MR. ZINK: But if you had a house that
4 wasn't labeling--?

5 MR. DROUILLARD: Sorry?

6 MR. ZINK: If you had a house that really
7 wasn't applying any kind of labeling at all--?

8 MR. DROUILLARD: If you were not applying
9 labeling?

10 MR. ZINK: If you weren't applying any kind
11 of labeling at all and you wanted to purchase this
12 system and put it in there, what would that cost?

13 MR. DROUILLARD: Well, if you were to lease
14 the system, it's going to range, and I'd hate to be
15 quoted on it because we haven't established -- well,
16 we have established somewhat of a cost control on this
17 -- it would be around \$1,500 per lane, per head, per
18 month, okay.

19 MR. LANDA: Thank you.

20 Our next speaker is Charles Hall with the
21 Georgia Fruit and Vegetable Growers Association.

22 MR. HALL: Thank you for the opportunity to

1 be here. My name is Charles Hall. I am executive
2 director of the Georgia Fruit and Vegetable Growers
3 Association.

4 Our association represents more than
5 300 fruit and vegetable growers in Georgia and the
6 Southeastern U.S. Fruit and vegetable production in
7 Georgia provides economic value to the state of more
8 than \$950 million at the farm gate.

9 In light of the recent foodborne illness
10 outbreaks, food safety is at the forefront of our
11 industry as we work to reinsure confidence in
12 America's food supply, particularly our fruits and
13 vegetables.

14 Our goal must continue to remain constant as
15 we strive to reduce incidences of foodborne illnesses
16 within the industry. Food safety education has always
17 maintained an important position in our association's
18 program of work.

19 In January 2002, our association was awarded
20 a grant from the Georgia Department of Agriculture to
21 develop and audit inspection procedure for our
22 growers.

1 This was started primarily because of
2 third-party audits and the high cost to the growers
3 for the third-party audits. This was done in
4 conjunction with the University of Georgia, the
5 Georgia Department of Agriculture, and the Georgia
6 Crop Improvement Association.

7 The Georgia GAP Food Safety Program provides
8 hands-on training and consultation to implement GAPs
9 and standard operating procedures for on-farm food
10 safety. This training and consultation is followed by
11 an inspection by a certified third-party auditor from
12 the Georgia Crop Improvement Association.

13 The scientific basis that the Georgia GAP
14 Program has developed using the Food and Drug
15 Administration's "Guide to Minimize Microbial Food and
16 Safety Hazards for Fresh Fruits and Vegetables"
17 published in October 1998, the program focuses on
18 eight areas in the growing and handling of produce to
19 minimize and eliminate food safety risk.

20 Although this is a voluntary program for
21 Georgia growers, our goal is to reduce farm risk and
22 ensure consumer confidence in Georgia produce. As

1 several other industry associations have stated today,
2 we believe there is a critical need here in our nation
3 to develop basic principles that will develop and
4 improve the confidence in a secure and safe food
5 supply.

6 These principles provide a basis for which
7 the produce industry and the U.S. Government can
8 develop a food safety policy framework. The
9 principles include, first, food safety standards must
10 be consistent for produce grown anywhere in the
11 United States or imported into this country.

12 Consumers must have the confidence that
13 produce grown in New York is just as safe as produce
14 grown in Georgia.

15 The same science-based standards that are in
16 place with the Georgia GAP Program must be applied
17 across the industry, if we are to be successful in
18 maintaining consumer confidence.

19 Secondly, to achieve consistent safety
20 standards across the industry will require these
21 standards to be mandatory with Federal Government
22 oversight.

1 We believe that food safety standards must
2 be based on sound science. FDA, as the public health
3 agency charged by law with ensuring the safety of the
4 nation's food supply including fruits and vegetables,
5 should determine those safety standards in an open and
6 transparent process with input from industry, the
7 scientific community, academic researchers, consumers,
8 and growers.

9 Standards developed should allow for a
10 commodity-specific food safety regulatory based on the
11 best available science. Food safety regulations must
12 have scientific flexibility to address the needs of
13 different commodities in different geographic regions.

14 I was very pleased to hear one of the
15 speakers today say a one-size-does-not-fit-all
16 approach is best way, because it is. We cannot have a
17 one-size-fits-all approach because it will not address
18 the individual specific needs of different commodities
19 within their own production and handling practices.

20 Our association believes these three
21 principles are very important as we try to reestablish
22 the confidence, the American consumers' confidence and

1 restoring their public trust in our fruit and
2 vegetable industry.

3 While a science-based, commodity-specific
4 food safety regulatory policy is our most immediate
5 need in our industry, we must not overlook the need
6 for additional research to address many of the issues
7 we face today.

8 Many of the speakers have addressed this,
9 but as an industry: we need a better understanding of
10 ways to reduce E. coli in cattle, better ways to
11 prevent contamination in the field, more effective
12 risk reduction techniques after harvest and in the
13 packing areas.

14 The Georgia Fruit and Vegetable Growers
15 Association strongly supports and will work with our
16 congressional delegation to seek increased funding for
17 food safety research.

18 In addition, we will support and work
19 diligently to seek increased research funding for
20 specialty crops including our food safety needs in the
21 2007 farm bill debate.

22 In closing, I thank you for the opportunity

1 to present our views on this very important topic. It
2 is our association's goal that we as an industry work
3 together with government to ensure that American
4 consumers have no fear of illness as they enjoy
5 nutritious and healthy fruits and vegetables.

6 Thank you.

7 (Applause.)

8 MR. GUZEWICH: This is Jack Guzewich with
9 FDA. I think by now you know what my question is
10 going to be.

11 MR. HALL: Yes, sir.

12 (General laughter.)

13 MR. GUZEWICH: I'll ask it again, just in
14 case. Do you think Georgia growers understand the
15 GAPs and are implementing them?

16 MR. HALL: I think, based on what growers
17 you're talking about, sir, within our blueberry
18 industry we probably have 80 to 85 percent of our
19 growers that are GAP certified and they are very, very
20 prevalent and knowledgeable of that, the peach
21 industry the same way.

22 When you move into the vegetable industry,

1 you go from a very small grower to a very large
2 grower, so it varies from that. I think most of our
3 growers are much more knowledgeable than they were six
4 months ago or certainly two years ago.

5 Most of what we have found, as we have
6 worked with food safety and with our Georgia GAP
7 Program, this is driven by what is demanded of the
8 grower. That's why we feel like a mandatory program
9 is necessary.

10 Most of the food safety issues and most of
11 our GAP Program was initiated because our customers
12 were saying, "You have to have a third-party audit."
13 Without the customer saying you had to have a
14 third-party audit, most of our growers wouldn't have
15 gone to that.

16 The larger ones would have, but the smaller
17 ones would not have gotten to that point. It has to
18 be driven. We don't like to pay taxes. We wouldn't
19 pay taxes if we didn't have to. A grower is not going
20 to go through the process of being audited, if they
21 don't have to.

22 MR. GUZEWICH: Thank you.

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1 MR. BACA: I have a question. This is
2 Joe Baca with FDA.

3 MR. HALL: Yes, sir?

4 MR. BACA: I guess my question is a very
5 basic one. When these audits are conducted, is there
6 any testing that is done? I know that observations
7 are made, but are there any samples taken?

8 MR. HALL: There are water samples taken.
9 It's taken by the auditor or either our staff member
10 that has worked with that grower. We are basically
11 providing a consulting and training operation, and
12 then the Georgia Crop Improvement Association who also
13 certifies seed in Georgia, the organic program in
14 Georgia. That's why it has worked because they have
15 the auditing background from that standpoint.

16 MR. LANDA: Our next speaker is Sally
17 Greenberg with Consumers Union.

18 MS. GREENBERG: Good afternoon. My name is
19 Sally Greenberg. I am senior counsel in the
20 Washington Office of Consumers Union. We are the
21 nonprofit publisher of "Consumer Reports" magazine,
22 with 4 million subscribers and "Consumer Reports

1 Online" with more than 2.5 million online subscribers.

2 I appreciate today's opportunity to
3 participate in this public conversation with the FDA
4 about the safety of fresh produce. I must say I'm
5 learning a lot from my fellow speakers.

6 I am here today to bring you another
7 consumer perspective. You have heard from some of my
8 consumer colleagues. What we want to say from the
9 Consumers Union and "Consumer Reports" perspective is
10 that in the last 5 months along more than 200 unlucky
11 consumers across 26 states ate spinach contaminated by
12 a particularly virulent form of E. coli that killed as
13 many as five and hospitalized more than 100 and
14 sickened another 100.

15 This spinach disaster was quickly followed
16 by a salmonella outbreak from contaminated tomatoes
17 served at a restaurant which sickened 183 people in
18 21 states.

19 On the heels of this, came yet another
20 E. coli outbreak from shredded lettuce at Taco Bell
21 and Taco John's restaurants that sickened another
22 152 individuals.

1 Consumers are understandably confused and
2 they are angry. They are angry that eating leafy
3 green vegetables and other produce can make them sick
4 and can even kill them.

5 Consumers Union believes that the time for
6 voluntary industry guidelines have long past.
7 Clearly, the FDA's voluntary approach to regulation of
8 fresh vegetables has utterly fail to make them safer.

9 We believe the FDA must assume the authority
10 and be given the staff to effectively mandate good
11 agricultural practices or "GAPs" for every farm and
12 hazard analysis, critical control point, or HAACP
13 Programs for every processor including thorough and
14 regular inspection programs, effective traceback
15 systems, third-party audits, and rigorous enforcement
16 standards.

17 The leafy green industry in particular has
18 brought dangerous products to market too many times
19 for consumers to believe that it will suddenly meet
20 voluntary standards. For many consumers, it's just
21 safer to stop buying leafy green vegetables, health
22 diet notwithstanding.

1 In the absence of strong FDA mandates to
2 regulate the produce industry, growers in states are
3 stepping in to fill the void. As I was on vacation
4 last week, I opened up "The Palm Beach Post" and saw
5 an article about which the subject was addressed by
6 Mr. Brown today of the Florida Growers Association.

7 What he told us and what I read in that
8 article was that in Florida where more tomatoes are
9 grown than in any other state, the growers there are
10 backing a bill to require mandatory state inspections
11 and traceback systems.

12 As for the California growers voluntary
13 agreement with the state officials there. We joined
14 with the trucker who spoke today. We are not fans of
15 that agreement because it lacks transparency and
16 because there is no public input and for a host of
17 other reasons.

18 Simply put, if the produce industry ever
19 hopes to regain consumer trust, it must be regulated
20 by an authority other than itself. The safety of the
21 food we buy is a fundamental expectation of consumers,
22 and the Government must use its standard-setting,

1 investigative and enforcement powers to see that this
2 expectation is fulfilled, nor should safety be used as
3 marketing tool when it comes to food.

4 Safety should not be something that
5 consumers must search out and possibly pay extra for,
6 for a variety of reasons, including that would leave
7 poor consumers and poor communities at risk.

8 Now is the time for the FDA to do everything
9 in its power including seizing adulterated products as
10 authorized by Section 402 of the Food, Drug, and
11 Cosmetics Act and establishing HACCP Programs on farms
12 as authorized by Section 361 of the Public Health
13 Services Act, all to ensure the safety of produce.

14 Further, Congress must step forward and
15 fully fund the FDA, giving the Agency the resources
16 and staff to effectively enforce mandatory authority
17 over this industry.

18 Former FDA Official William Hubbard wrote
19 last year in "The Washington Post" that the Agency's
20 food inspections have dropped from 50,000 in 1972 to
21 about 5,000 in 2006, a 90 percent reduction
22 inspections.

1 He also said that U.S. food processors are
2 inspected on an average of every 10 years and that the
3 chance of a food product from overseas being inspected
4 is infinitesimal. Hubbard explained that for years
5 the FDA's budget has remained essentially flat while
6 new responsibilities have been piled on.

7 I want the FDA officials here to know that I
8 and other consumer groups spend a lot of time in
9 Congress. One of the things that we continue to do is
10 ask Congress to increase the FDA's budget commensurate
11 with its expanded responsibilities.

12 To recap, the central components of
13 regulation ought to be GAPs for all farms and HAACP
14 Programs for all processors; written food safety plans
15 showing how producers will comply with GAPs;
16 third-party audits; traceback systems that include
17 package identifiers so that each item can be traced
18 all the way back to the field in which it originated;
19 FDA inspections at least yearly, made possible by
20 increased funds from Congress; and FDA enforcement
21 that has teeth.

22 I leave you today with a couple of

1 hundred-million-dollar questions from the consumer
2 perspective. The first one, why is the FDA only
3 suggesting and recommending safe practices for the
4 fresh produce industry and not requiring them despite
5 numerous incidences of contaminated fresh produce
6 reaching the marketplace and harming and even in some
7 cases killing consumers?

8 Secondly, how many more deadly outbreaks
9 must there be before FDA's "should" becomes a "must"
10 and their suggestions, recommendations, and current
11 thinking become rigorous, mandatory oversight by a
12 credible government watchdog that is well funded and
13 adamant about protecting the food supply and public
14 health?

15 While we are waiting for credible answers to
16 these questions, consumers' health and safety hangs in
17 the balance. I thank you.

18 (Applause.)

19 MS. GREENBERG: Did I get a pass?

20 MR. LANDA: Yes.

21 MS. GREENBERG: Thanks.

22 MR. LANDA: Our next speaker is

1 Robert Gravani with Cornell University.

2 MR. GRAVANI: Well, good afternoon. Thank
3 you very much for the opportunity to speak with you
4 today. Although I am director of the National Good
5 Agricultural Program that's housed at Cornell
6 University, we have 25 states' worth of collaborators
7 out there at mostly land-grant universities.

8 Today, the comments that I will make will
9 represent my views and the views of my colleague
10 Ms. Betsy Bihn. We certainly heard a lot today about
11 regulation and certainly the concern out there about
12 regulation is that small and medium growers are very
13 concerned.

14 They are concerned about the metrics, many
15 of which are based on old science, and they are
16 certainly concerned about the issues of compliance.
17 They are concerned about who will enforce those
18 regulations, and that's a key issue that we need to
19 face today.

20 Do we have enough people who are properly
21 trained to go out there and enforce those regulations
22 should we pass them? Would regulations be the best

1 use of financial resources given all of the current
2 needs we've heard here today?

3 I want to call your attention to the
4 excellent presentations we heard this morning, one in
5 particular by Dr. Jim Rushing a colleague and
6 collaborator from Clemson University.

7 There is a lot of wisdom in Jim's
8 statements. I'm going to follow up on some of those
9 points, because when you're next to last most of your
10 good ideas have already been presented.

11 Basically, let's look at some things. The
12 current FDA guidance is not always followed, Jack. A
13 lot of growers are unaware of the standards and
14 expectations.

15 This might not be the largest growers in our
16 country, but it certainly represents a number of
17 growers. We and our collaborators throughout those
18 25 states have conducted numerous GAPs workshops for a
19 variety of commodity groups and growers throughout the
20 country. However, there are still people who are
21 unaware of the standards and the expectations and are
22 not implementing GAPs.

1 Third-party audits, and there are a ton of
2 companies that are out there auditing farms, but there
3 is no standardization in the audit forms. Multiple
4 audits are often done on the same farms at great
5 expense, for what reason, auditing the same things.

6 We have heard a lot about this today. There
7 are no standard audit training programs for auditors.
8 Yes, the USDA has a very good mentoring program and
9 audit procedure system program where investigators
10 certainly go through and mentor with experienced
11 inspectors, et cetera. Let me give you a case in
12 point.

13 We got a call from an irate grower at one of
14 our GAPs workshops and he said, "I got dinged because
15 I didn't wash my produce." His produce was onions.
16 Okay? Does that tell you something about standards of
17 audits and auditors?

18 Some food safety standards out there are
19 based on non-food safety related research. Think
20 about irrigation water standards, which are a real
21 tough one to get our arms around.

22 We are looking now at recreational water

1 standards to be applied to irrigation water standards.
2 Clearly, we have got some issues out there on the
3 research side.

4 I think, and I commend all the groups out
5 there who are really looking very at those research
6 gaps, no pun intended. We need to identify those
7 areas that are most important that require research,
8 and we need to support these financially.

9 I want to publicly mentioned Fresh Express
10 who put up \$2 million unencumbered and brought
11 together a group of scientists to allow them to write
12 an RFP and give that money away to researchers who
13 could, in a very short period of time, come up with
14 some answers in one year. You will see some materials
15 about that released next week.

16 I think we need to continue to support those
17 levels of research. We need to continue to
18 consistently support education and training programs
19 for growers.

20 While these are done intermittently based on
21 competitive grants for two or three years at a time,
22 we really need to consistently support education and

1 training for all growers, large and small and medium
2 throughout the United States, not in just selected
3 states.

4 We need to understand, as many of the
5 speakers previously have mentioned, that diverse
6 production and distribution channels for different
7 types of produce, from different geographical areas
8 and certainly commodity-specific documents are
9 important.

10 We have got to recognize that there are many
11 small and medium operations providing fresh fruits and
12 vegetables in the U.S. that reach an awful lot of
13 consumers.

14 With that, I want to thank you again for the
15 opportunity to say a few words today.

16 (Applause.)

17 MR. GUZEWICH: Do you want to answer my
18 question?

19 MR. GRAVANI: Ask it again, Jack, because I
20 want to have another crack at it.

21 (General laughter.)

22 MR. GUZEWICH: Okay. Lest Bob you feel left

1 out -- this is Jack Guzewich with FDA -- Bob, do you
2 think growers are implement and understand GAPs?

3 MR. GRAVANI: Jack, I think it's a little of
4 both. I think just a lot of people out there who have
5 an inconsistency in terms of their knowledge of GAPs,
6 but I also think there are some implementation issues
7 out there.

8 As Caroline mentioned this morning, we did a
9 growers survey in 2002 and 2003, reported out in 2004.
10 There was still a lot of people, despite all our
11 efforts and hard work and all the materials on our
12 great website that we make available, people still are
13 in some cases clueless about what we are addressing.
14 That's important. We need to have, that's why I say a
15 consistent education and training effort nationally,
16 not just in selected states.

17 MR. LANDA: Mike Landa. What do you think
18 accounts for that, to use your word, "cluelessness"?

19 MR. GRAVANI: I think that some people as
20 many speakers previously have described is that "We've
21 always done it this way." To go back to Jim's
22 Rushing's comments, "We've always done it this way."

1 We've never had a problem. So why should we spend
2 this time, labor, and manpower recordkeeping issues to
3 address these issues.

4 We need to impress upon these folks the
5 reasons why we need to do this. Obviously, the
6 recalls and the illnesses and deaths are a great way
7 to get people's attention, certainly.

8 DR. SOLOMON: Steve Solomon, FDA. We are
9 having these issues you described here domestically.
10 What do you think the approach should be
11 internationally?

12 MR. GRAVANI: I think education and training
13 internationally, too, and I commend the JFSAN/FDA
14 consortium for conducting programs in a number of
15 countries. I think we need to take the next step and
16 continue to provide some good, science-based metrics
17 now. I agree with Jim.

18 If we look at the data and we look at what
19 we are asking people to do, we can't answer a lot of
20 the questions. We really need to provide them with
21 better science and more information about how to
22 comply and how to reduce the risk on the commodities

1 that we are talking about here today.

2 Thank you very much.

3 MR. LANDA: Thank you.

4 (Applause.)

5 MR. LANDA: Our next speaker is Jenny Scott
6 with Grocer Manufacturers/Food Products Association.

7 MS. SCOTT: Good afternoon. My name is
8 Jenny Scott and I'm vice president of Food Safety for
9 the Grocery Manufacturers Food Products Association,
10 which represents the world's leading food, beverage,
11 and consumer products companies.

12 We promote sound public policy and champion
13 initiatives that serve to protect the safety and
14 security of the food supply through scientific
15 excellence.

16 Thank you for the opportunity to provide
17 comments on the safety of produce from the perspective
18 of processors who use produce as an ingredient and who
19 produce fresh-cut produce products for retail and food
20 service as well as those who are customers and provide
21 produce to the consumer through food service
22 operations.

1 FDA posed questions in a number of areas,
2 and I only intend to comment briefly on a couple of
3 them. First, we commend FDA for having these public
4 meetings as they bring to light how much we really
5 don't know about the safety of food grown on the farm
6 and controlling pathogens in those products.

7 FDA developed its final guidance on good
8 agricultural practices in 1998. In it's good
9 guidance, there is a lot of discussion about what else
10 needs to be done. One of the things we do need to do
11 is to determine the extent to which good agricultural
12 practices for fruits and vegetables have been properly
13 implemented. Procedures to verify compliance need to
14 be established.

15 Second, the produce industry needs to work
16 together to share food safety best practices for
17 production and processing. They need to embrace the
18 concept that food safety cannot be a competitive
19 issue.

20 The produce industry, including growers and
21 processors, needs to be proactively developing and
22 utilizing technologies and processes that create

1 sufficient interventions in reducing or eliminating
2 food safety hazards to ensure the safety of fresh
3 produce.

4 Currently, many U.S.-based organizations are
5 working on establishing guidelines or standards
6 relative to good agricultural practices, to
7 manufacturing practices, and audit programs for
8 produce growers and processors. We have a long way to
9 go in these.

10 We need to have harmonized, HACCP-based good
11 agricultural practices based on the best science
12 available; although, there will be some
13 commodity-specific aspects.

14 It is going to be more productive to have a
15 single set of best good agricultural practices for the
16 growers in the industry to use. These good
17 agricultural practices need performance criteria
18 against which compliance could be measured, and these
19 need to be widely vetted and agreed upon. As you have
20 heard here today, we have a long way to go in
21 attaining those appropriate criteria.

22 This would be an ideal project to take to

1 the National Advisory Committee on Microbiological
2 Criteria for Foods and put it on a fast track. A lot
3 of people think that the committee takes years to
4 finish their deliberations on things, but they can
5 work quickly when they are given the resources to do
6 so.

7 One of the questions posed in "The Federal
8 Register Notice" about this meeting was, "What new
9 federal actions, if any, are needed to enhance the
10 safety of fresh produce?"

11 FDA should move forward with its
12 modernization of its current good manufacturing
13 practices and pay particular attention to produce in
14 this regulation and include provisions that apply to
15 produce commodities where needed.

16 This could include a requirement that
17 produce be produced under good agricultural practices.
18 Another regulatory action deals with recordkeeping
19 procedures which should provide accurate tracing both
20 forward and backward along the supply chain.

21 FDA already requires the ability to track a
22 product one step forward, one step back and thus apply

1 all along the food chain. We suggest that FDA host a
2 public meeting to exchange ideas on what is possible
3 in tracing produce throughout the food chain. We have
4 heard a little bit of that today, but there is a lot
5 more out there that can be applied.

6 It does have to be recognized that for many
7 products tracking to particular fields may be very
8 difficult due to comingling. It is not possible to
9 completely avoid comingling in the way we do business
10 today.

11 FDA should also host a meeting to explore
12 microbiological testing related to produce. It would
13 address such questions as: what is the role of
14 indicator organisms? How do you obtain representative
15 samples from fields? What do you sample in the field?
16 When is the best time to sample a field? What's an
17 indicator of a problem in water testing? When should
18 water be tested?

19 There are lots of questions, and this may be
20 another issue for the National Advisory Committee on
21 Microbiological Criteria for Foods.

22 One final federal action relates to

1 training, which is an essential component to ensure
2 proper implementation and execution of good
3 agricultural practices.

4 FDA should mandate in its modernized GMPs
5 that every farm should have at least one person with
6 good agricultural practice training who is responsible
7 for oversight of operations. Records of training
8 should be maintained.

9 To most effectively minimize the risk of
10 future foodborne disease outbreaks and improve
11 consumer confidence in fresh produce, knowledge and
12 technology gaps must be filled.

13 Federal monies should be dedicated towards
14 this research as well as towards the extension
15 programs that provide outreach and training to
16 growers, packing houses, processors, and the workers.

17 Partnerships among industry, government, and
18 academia, in particular through the land-grant
19 university system offer the best opportunity to
20 develop practical solutions.

21 It is equally important that substantive
22 consumer outreach programs be conducted and enhanced

1 to emphasize the importance of proper food handling.
2 We recognize that this will take funding, and that's
3 why as part of the Coalition for a Stronger FDA, we
4 support significant and sustained funding increases
5 for FDA's Foods Program. We intend to do all we can
6 at GMA and FPA to work with all stakeholders to
7 enhance the safety of produce in the United States.

8 Thank you.

9 (Applause.)

10 MR. LANDA: Questions?

11 (No verbal response.)

12 MR. LANDA: You get a pass.

13 I think we have one more speaker, a person
14 without indicated a desire to speak earlier today,
15 Jill Hollingsworth from the Food Marketing Institute.

16 MS. HOLLINGSWORTH: Thank you. First, I
17 want to thank FDA for having this public hearing; and,
18 secondly, I want to apologize to the panel for making
19 you stay five more minutes. I'll try to do it really
20 quick.

21 I'm Jill Hollingsworth. I'm the vice
22 president of food safety for the Food Marketing

1 Institute. We are the trade association that
2 represents the retail food stores. Our membership
3 includes a little over 1,500 supermarket chains,
4 independent-operator grocery stores, and also the
5 wholesale companies that supply to them. Our
6 membership represents over 75 percent of all retail
7 food store sales in the United States.

8 Retailers are in a unique position in the
9 food chain. On the one hand, we meet and greet
10 customers, the consumer, every day -- oftentimes,
11 24 hours a day, 7 days a week.

12 On the other hand, we also have the
13 purchasing power. We actually are purchasing agents
14 for the consumers, and we can use that position to
15 influence suppliers of the food chain.

16 We realize that retailers, in fact, can be a
17 catalyst for change and for improvements, and we have
18 seen this. There are numerous examples of where the
19 retail food industry has actually brought about
20 changes, for example, requiring test-and-hold programs
21 for ground beef and even changing animal welfare
22 standards.

1 We also work closely with our supplier
2 partners. To that end, we have supported all of the
3 work that the leafy-green initiatives have achieved so
4 far such as the metrics, the marketing orders, and
5 other similar efforts to improve these products.

6 We also applaud FDA and the states for their
7 continued effort on improving GAPS and GMPs, but we
8 feel they just haven't gone far enough. We are
9 looking at past experiences, ground beef and seafood,
10 to try to learn lessons from the past and move forward
11 with the leafy-green industry.

12 One of the things that we want is a
13 HACCP-based, leafy-green guidance. We have
14 established one under a retail-owned program called
15 Safe Quality Food or "SQF."

16 Recently, a group of industry stakeholders
17 and scientists convened to do a complete risk
18 assessment of the leafy-green products from harvesting
19 through processing.

20 Yes, we know some people will say you can't
21 use HACCP because there aren't always CCPs, but
22 certainly the methods and the techniques that are used

1 in a HAACP-based program and the risk assessment
2 efforts that can be applied to any food commodity have
3 worked very well in assessing the leafy-green
4 industry.

5 We have incorporated all of the work that
6 has been done in the past, the good agricultural
7 practices and manufacturing practices. We will also
8 be able to incorporate any regulatory standards should
9 they be developed.

10 But, again, the SQF standard will go
11 further. We know we don't have all the science, we
12 wish we did, but we can't tell consumers that they are
13 going to have to wait until we have more science. We
14 have to do what we can do now with the science that we
15 have.

16 One of the things we have done in the SQF
17 Program is include rather stringent verification and
18 validation steps. Yes, we will expect there to be
19 microbiological sampling and testing of the product,
20 but that data will serve us in many ways.

21 Not only can that microdata be used to
22 validate whether a supplier's food safety plan is

1 actually working, but it will also help us establish a
2 baseline, one of the things the scientists keep
3 telling us is the missing piece. Against that
4 baseline we will be able to truly measure if we are
5 making continuous improvements.

6 As a retailer-owned standard, one of the
7 nice things about SQF is that we can avoid all of the
8 conflicts that are inherent in many of the industry's
9 other driven standards.

10 We can also make changes quicker, certainly
11 quicker than the federal government. We know they try
12 to make changes quickly, but they do have a lot of
13 regulatory procedures they have to abide by.
14 Additionally, we think we have a better plan for how
15 to conduct audits.

16 SQF is not just an audit program. It is
17 actually an international certification program. Only
18 accredited certification companies are allowed to
19 perform the audits.

20 The certification companies must be
21 accredited by an international body such as ANSI,
22 UCAS, or a similar program. All of the auditors must

1 be trained. They must be registered with SQF and they
2 must demonstrate competency in the product that they
3 are going to audit. In other words, we don't let meat
4 auditors go onto a farm and look at spinach.

5 Also, because SQF is an internationally
6 recognized program already, we are able to use it in a
7 number of other commodities and in any country around
8 the world.

9 Already many products around the world in
10 Chile, Mexico, and other places are already being SQF
11 certified. We believe that the SQF Program and the
12 guidance we have developed for leafy greens will move
13 us in the right direction, the direction of food
14 safety, safer products, safer leafy greens, and
15 greater consumer confidence in the products we sell at
16 retail.

17 Thank you.

18 (Applause.)

19 MR. GUZEWICH: This is Jack Guzewich with
20 FDA. I get to ask my question to ask my question one
21 more time.

22 (General laughter.)

1 MR. GUZEWICH: Since, Jill, you're involved
2 in SQF, do you have any impressions on the
3 implementation and understanding of GAPs in
4 agriculture in the U.S. internationally?

5 MS. HOLLINGSWORTH: As far as what is
6 currently being done, one of the first things we do in
7 the SQF Program is we require the company to compare
8 the program they have in place now with the SQF
9 standard and identify what GAPs they have in between
10 the two.

11 We have found that particularly in fresh
12 produce there is quite a bit of difference, a lot of
13 companies that have not implemented GAPs, certainly
14 very few of them who have gone far enough to do
15 validation and verification of the steps they are
16 using.

17 MR. GUZEWICH: Thank you.

18 MR. LANDA: Thank you.

19 MS. HOLLINGSWORTH: Thank you.

20 MR. LANDA: Well, that concludes the
21 presentations by our speakers this afternoon. I would
22 like to thank them as well as the people who presented

1 this morning. I would like to thank you for coming
2 and staying with us all day. It's been a long day.

3 I would like to thank Juanita Yates, who as
4 the top of the stairs there, and her stairs for taking
5 care of the logistics.

6 (Applause.)

7 MR. LANDA: Finally, I would like to
8 encourage you and remind you that the docket is open
9 to June 13 and to encourage you to submit comments,
10 information, data.

11 There obviously isn't a five-minute limit on
12 that, but more importantly I suppose there is no page
13 limit, so you can submit as much information as you
14 like.

15 Thank you again. This concludes the
16 proceedings today.

17 (THEREUPON, at 4:30 p.m., the meeting was
18 concluded.)

19 * * *

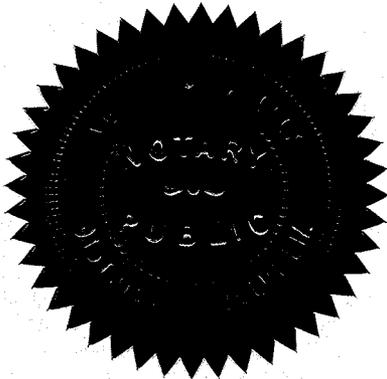
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I, OVEDA V. HANCOCK, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in stenomask and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by and of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



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Notary Public in and for
the District of Columbia

My Commission Expires:
June 29, 2008