

1 further supports use of voluntary labelling of foods both
2 those that are bio-engineered and those that are not
3 provided such statements are truthful, non-misleading and
4 disclose the necessary acquired material facts.

5 To this end we would recommend that when any
6 voluntary statements are used such as biotech free or
7 contains biotech ingredients, three criteria must be met:
8 Number one, a detection or threshold limit to be determined;
9 Two, substantiation including identify preservation and
10 other trace back procedures; and Three, disclosures or
11 accompanying statements to avoid deception.

12 In conclusion, there are two questions that need
13 to be address. Could and should the process be more formal
14 and transparent? Yes. Are criteria needed? Yes. Thank
15 you very much.

16 MR. ROBERT LAKE: Next. Go ahead.

17 MS. PATRICIA COX: Thank you. Finally I get to
18 speak. Okay. I just wish to continue reporting concerns
19 about the genetically engineered foods expressed by the
20 FDA's own --

21 MR. ROBERT LAKE: Could you identify who you are
22 and then also please speak into the microphone so that
23 others can hear you?

24 MS. PATRICIA COX: I've never had a problem being
25 heard before. Okay. Yes, I will. Do I get to start over?

1 MR. ROBERT LAKE: Go ahead.

2 MS. PATRICIA COX: Okay. I'm Patricia Cox, I'm a
3 consumer. I came here just not trusting the FDA now I'm
4 terrified of the FDA. In a memo to Dr. Mary Asky [phonetic]
5 on February the 5th, 1992, Director of the FDA's Center for
6 Veterinary Medicine, she received a memo writing on behalf
7 of himself and other scientists at the department wrote that
8 "Ample scientific justification to support free market
9 regulations on bio-engineered foods as a new additive", and
10 he continued, "the Center for Veterinary Medicine believes
11 that animal feeds derived from a genetically modified plants
12 present unique animals and food safety concerns."

13 Another scientist Dr. Lewis Preable [phonetic] of
14 the FDA's microbiology group wrote "There is a profound
15 difference between the types of unexpected affects from
16 traditional breeding and genetic engineering." He added
17 that several aspects of the gene slicing may be "more
18 hazardous". Also Dr. Irvin Mathews of the FDA's
19 toxicologist warned about the generation of "unexpected
20 toxins that could be uniquely different chemicals that are
21 usually expressed in unrelated plants". He cautioned that
22 detecting such unexpected toxins could be very difficult.

23 The Division of Food Industry and Toxicology is on
24 record of the same effect. I'd like you to be more aware of
25 what the scientists do say especially your own and the rest

1 of the world's opinion of this if you would please. And, I
2 would vote for the Natural Law Party which is very much
3 opposed to this genetically modified organisms. Thank you.

4 MR. ROBERT LAKE: Thank you, ma'am. Next.

5 MR. JEFFERY STEIN: I am Jeff Stein a molecular
6 biologist by training and Director of Regulatory and
7 Government Affairs for Novartis Seeds in North America.

8 We have a regulatory system in the U.S. that is
9 the model for regulatory systems worldwide. The coordinated
10 framework of which the 1992 policy is a component provides
11 for an exhaustive safety review of the DNA elements, new
12 expressed proteins and other components from crop plants
13 derived through genetic engineering technology. The degree
14 of scrutiny that these products undergo is unparalleled.

15 I've read reports that due to the perceived
16 inadequacies of the current regulatory system there is the
17 potential for the public to be exposed to a new allergen or
18 perhaps a new toxin or that food derived from these crop
19 plants will be of lower nutritional value. As someone who
20 has fostered two of these products through the U.S.
21 regulatory process, including two FDA consultation, I'm
22 frankly puzzled by these allegations.

23 Volumes of data are provided to three agencies
24 that includes toxicological studies and evidence addressing
25 the allergenicity potential of the newly expressed proteins.

1 Further, we analyze for every class of nutrient where
2 validated methods are available and have determined that the
3 nutritional composition is uncompromised. I contend that
4 the claims that these products are unsafe or less nutritious
5 are without scientific merit. If indeed there were safety
6 or nutritional concerns a system is in place to address them
7 and if necessary would require appropriate labelling.

8 I recognize that there is substantial pressure on
9 the Food and Drug Administration from various groups to
10 change from its present regulatory framework. However, I
11 urge this panel to recommend to the FDA that they stand
12 behind a regulatory process that works and one that has
13 proven to be effective in maintaining a safe and wholesome
14 U.S. food supply. Thank you.

15 MR. ROBERT LAKE: Thank you, sir. Next.

16 MR. TOM WALLACE: My name is Tom Wallace a farmer
17 from west central Illinois and today I represent the
18 Illinois Soybean Association. Illinois soybean producers
19 have worked hard to develop domestic and foreign markets for
20 soybeans and soybean products including soy protein and
21 soybean oil. We have also worked to establish the quality
22 reputation of soy products including the determination last
23 month by FDA that consuming soy protein in a diet can reduce
24 serum cholesterol and the risk of heart disease.

25 Soybean farmers would do nothing to put our

1 markets or our reputation at risk by supporting
2 commercialization of soybean varieties if they raise
3 legitimate science based questions about their safety for
4 consumers or for the environment. Soybean varieties
5 enhanced through biotechnology were introduced into
6 commercial production in the United States in 1996. They
7 have been broadly accepted and compromised an estimated 55
8 percent of total U.S. soybean acreage in 1999.

9 While current varieties express agronomic traits
10 the reduced production costs we fully anticipate future
11 biotech soybeans that will significantly benefit consumers
12 and producers alike. In addition to the economic benefits
13 one reason for the rapid acceptance of biotech soybeans by
14 producers is the safety reviews and approvals provided these
15 products by U.S. government regulatory agencies including
16 FDA.

17 Farmers are aware of the high credibility these
18 agencies have with American consumers and the confidence
19 that the public has in the safety of approved food products.
20 In this regard, any change in the process through which FDA
21 reviews applications for commercial introduction of biotech
22 products should be done for the purpose of strengthening
23 FDA's ability to assure consumers regarding their safety.
24 If replacing FDA's current voluntary review with mandatory
25 approval contributes to this goal without unduly impeding

1 the approval of biotech varieties supported by sound science
2 soybean producers would support such a change. Thank you.

3 MR. ROBERT LAKE: Thank you, sir. Next.

4 MR. MICHAEL LANNON: My name is Michael Lannon, I
5 represent myself. I greatly appreciate your individual
6 attention to this matter. I also thank you for allowing my
7 response regarding genetic engineering.

8 I am in every way opposed to genetic engineering
9 of foods. However, I am not about to cite the numerous
10 studies which back up and influence my standpoint. I find
11 no productive value in comparing my studies with your
12 studies.

13 Once upon a time there was a wonderful man named
14 Harvey Wiley who started the Food and Drug Administration
15 because he was certain that Benzene [phonetic], which was
16 being used as a solvent and a cheap way to make and preserve
17 foods and drugs was a cancer causing agent. He started the
18 FDA to eliminate Benzene. By the 30's the FDA eliminated
19 Harvey Wiley and reintroduced Benzene.

20 And here we are today, 60 something years later,
21 virtually behaving in the same manner. This, in my opinion,
22 is where the problem lies. Whether it be Benzene or genetic
23 engineering of foods is merely a symptom of the underlying
24 problem. Why do we continue to do business in this way?
25 The safety of your very own body is at stake. If I'm not

1 willing and if you're not willing to oppose genetic
2 engineering of foods who is? It starts with me. It starts
3 with you.

4 The cost to the environment and to personal health
5 from genetic engineering of foods is exorbitant and for the
6 most part unknown. If you decide genetic engineering of
7 foods is acceptable we'll pay for it later in environmental
8 cleanup, doctor medical bills and a host of many more
9 unknowns. We can't afford to put this expense over safe
10 food. There's a bigger picture out there. I highly
11 encourage you to embrace it.

12 It's a journey, a learning experience and an
13 opportunity to raise awareness and consciousness. It's a
14 passion for life and all living things. Do the right thing
15 at all costs. A Monsanto official told the New York Times
16 that the corporation should not have to take responsibility
17 for the safety of its food products. Monsanto is counting
18 on you to ensure the safety of this biotechnology. I am
19 counting on you to ensure the safety of the public. After
20 all, isn't this what Harvey Wiley had intended?

21 MR. ROBERT LAKE: Thank you, sir. Next.

22 MR. SCOTT FITZ: Thank you, Commissioner. I am
23 Scott Fitz a soybean and corn farmer from northwest Indiana
24 town of Winnamac [phonetic]. I'm a member of the board of
25 directors of the American Soybean Association, an

1 organization which represents 32,000 producing members on
2 national issues important to all U.S. soybean farmers.

3 U.S. soybean producers have worked hard to
4 establish the quality reputation soybeans enjoy with
5 consumers in the U.S. and around the world. If there were
6 any legitimate basis for questioning the safety of varieties
7 derived through biotechnology for animal or human
8 consumption or to the environment we would be the first to
9 raise concern. ASA fully supports the current process
10 through which FDA reviews the applications for commercial
11 introduction of biotech products.

12 If, however, replacing this voluntary process with
13 a mandatory approval would strengthen FDA's ability to
14 reassure consumers regarding the safety of these products we
15 would endorse such a change. Similarly, ASA would support
16 guidelines for voluntary labelling of foods as biotech free
17 or that do not contain biotech ingredients to help meet the
18 needs of consumers who want to buy these products.

19 We do not support mandatory labelling of products
20 made from biotech crops that have been declared
21 substantially equivalent to conventional non-biotech crops
22 in terms of safety, composition, nutrition and
23 allergenicity. Such mandatory labelling may not give
24 consumers useful information about the safety or nutrition
25 of the product but rather potentially stigmatize food

1 biotechnology based on unfounded and misleading claims.

2 We believe critics of this new technology have not
3 adequately considered the very real benefits agriculture
4 biotechnology brings to the environment. While we have made
5 great strides in reducing the toxicity and uses of
6 pesticides in recent years we hope our friends in the
7 environmental community can see that future biotech
8 innovations will allow us to improve even more. Thank you.

9 MR. ROBERT LAKE: Thank you, sir. Next.

10 MR. KERMIT MCCORMICK: Good afternoon. I'm Kermit
11 McCormick President of IMC Feed Ingredients. I also serve
12 as chairman elect of the American Feed Industry Association
13 of Arlington, Virginia. Food safety and the consumer
14 confidence in that food safety is the feed industry's number
15 one abiding priority. Close on its heels is the well-being
16 of our animals and the stewardship of our land.

17 Our industry routinely encourages, examines,
18 tests, retests, often rejects but more often embraces sound
19 technology meeting our three basic criteria: Is it safe for
20 man, animal and the environment? Does it do what it's
21 supposed to do? And is it economically viable? My company
22 and the feed and pet food industries support science based
23 food regulation. We support prudent government regulation
24 protecting public health but also benefiting industry.
25 FDA's 1992 voluntary consultation system allows companies to

1 share information about safety, nutrition, testing and
2 labelling prior to commercial release of biotech products.

3 The system appears to be working well with over 40
4 bio-engineers plants reviewed under this policy. Draught
5 and disease and insect resistance, strains of corn,
6 soybeans, fruits and vegetables, plant-based insulin
7 production and iron and Vitamin A enhanced rice are just a
8 few examples of success and promise of the technology and
9 testaments to FDA's review system. There appears to be no
10 immediate need to revise a successful system.

11 There is no compelling argument to make
12 consultations mandatory. We support as do nearly 40 other
13 national, agricultural and food organizations the current
14 federal labelling policy. Labelling for the sake of
15 labelling wastes government and private resources.

16 MR. ROBERT LAKE: Thank you, sir.

17 MR. KERMIT MCCORMICK: Thank you.

18 MS. ERICA RENAUD: Hello. My name is Erica Renaud
19 I am representing Frontier Natural Products Co-op in Norway,
20 Iowa. We're a 40 million dollar company that manufactures
21 and distributes organic and inorganic herbs, spices, coffee
22 and food products. I don't feel that I'm solely
23 representing the organization with which I work for because
24 as we are a co-op we have 15,000 other member co-ops that
25 are members of our co-op. And in addition, we have hundreds

1 of organic and inorganic farmers that grow for us.

2 We are actively attempting to source non-GMO crops
3 for our products and we're finding this really difficult and
4 are considered the possibility of voluntarily labelling our
5 own products because we don't want to risk the demands of
6 our consumer and those that are really care for their
7 personal health and the health of the environment. As many
8 of us know the organics industry is growing at 20 percent
9 annually and most recently there has been a demand for no
10 GMOs in the organic standards.

11 We are very concerned about some of the studies
12 replicated or non-replicated that support that there are
13 potential negative impacts to human health through
14 allergens, residual DNA, cancer through -- and other
15 potential implications of the change in nutritional values
16 of crops. And we feel that there is a lot of value in the
17 human experience and that it should not only be solely
18 identified through replicated research.

19 We would like to see labelling on all products
20 that are potentially GMO'd and all species indicated that
21 are within that process. In addition to that, we want to be
22 supporters or restorative agriculture and not destructive
23 agriculture. And I myself am an organic farmer and
24 researcher and really -- Oh, sorry.

25 MR. ROBERT LAKE: Thank you, ma'am. Next.

1 MS. FELICIA BUSCH: Thank you for the opportunity
2 to provide input today on behalf of the consumers that I
3 work with. My name is Felicia Busch, I'm a registered
4 dietitian. Every day my staff of eight RDs reach scores of
5 people interested in health and nutrition issues through our
6 work site education programs, adult education classes and in
7 grocery stores where we provide nutrition information
8 directly to shoppers at point of purchase.

9 Our experience is that for the vast majority of
10 consumers biotechnology is not an issue. Daily we field
11 questions from consumers on nutrition and health not once in
12 the last five years has the issue of biotechnology been
13 raised by any of the consumers that we meet with. Perhaps
14 the only individual consumers who are voicing opinions are
15 the professional activists and those people who have been
16 randomly selected to participate in the many surveys
17 reported on today.

18 Educated consumers are overwhelmingly supportive
19 of this advancement in cross breeding that can reduce the
20 use of pesticides and other agricultural chemicals, can
21 increase the nutritional value of foods and help ensure the
22 safety and lengthen the shelf life of perishable foods.
23 There's no doubt that the benefits of food biotechnology are
24 enormous. I would ask the FDA to take the lead roll in
25 educating consumers about the facts of biotechnology. I

1 would recommend that you continue to consults with
2 scientists and to ground your decisions based on sound
3 science.

4 And then finally I would suggest that you consider
5 allocating your limited resources to more pressing,
6 broad-based consumer issues such as food safety and the
7 regulation of known harmful substances including drugs and
8 other products that are currently allowed to masquerade as
9 dietary supplements. Thank you.

10 MR. ROBERT LAKE: Thank you, ma'am. Next.

11 MS. MARY LEE CHIN: My name is Mary Lee Chin I'm a
12 registered dietician who has worked with patients and the
13 public for over 26 years with a specialty in pediatrics,
14 adolescent medicine and chief clinical dietician in the past
15 of a children's diabetes clinic. I address my remarks today
16 on a narrow focus of the foods called functional or enhanced
17 foods that can be produced through food biotechnology.

18 I find that my patients and the consumers are
19 turning to enhanced foods or functional foods to better
20 treat their health, to decrease risk of chronic disease and
21 to treat illnesses. As a result many people put their trust
22 and spend their hard earned money purchasing products of
23 dubious value such as split pea soup fortified with St.
24 John's Wart, ice cream supplemented with econacia
25 [phonetic]. I get questions from patients who've been told

1 by a neighbor that their kid should be chewing brain gum or
2 snacking on ginseng energy bars.

3 The problem is that these products have no studies
4 to substantiate their efficacy and ineffective regulation.
5 And I can only describe myself as bemused the day a parent
6 came in and wanted to know about Aloe Vera injections for
7 her diabetic child as advocated by her hair dresser.
8 Conversely, food biotechnology products based on sound
9 scientific research and subject already to a full array of
10 effective regulatory rules and regulations and oversight
11 exist for safety.

12 The technology has the potential to produce foods
13 with enhanced nutritional value such as rice with a better
14 amino acid profile or foods with increased health promoting
15 components. So, clearly based on sound research and meeting
16 stringent food safety standards many of these foods will
17 help people decrease their risk of disease and contribute to
18 a healthier population. The labelling already exists for
19 this food. The new foods have regulations that will need
20 identify that they are new and those regulations are
21 effective and already exist. I look forward and welcome the
22 opportunity to recommend these new food products for
23 patients.

24 MR. ROBERT LAKE: Thank you, ma'am. Next.

25 MR. GARY P. MUNKVOLD: My name is Gary Munkvold,

1 I'm an associate professor in plant pathology at Iowa State
2 University. I'd like to address a particular issue related
3 to the safety of BT corn and corn in general. For the past
4 six years I've been conducting research on microtoxin
5 producing fungi in corn.

6 Microtoxins are chemical substances produced by
7 fungi and they're toxic or carcinogenic to humans and other
8 mammals. Among the microtoxins that can be found in corn
9 are alfa toxins and fumonasins [phonetic]. In the United
10 States millions of bushels of corn are rejected by buyers
11 each year because of unacceptably high alfa toxin levels.
12 In developing countries standards are less strictly enforced
13 and unacceptably high levels of alfa toxin commonly enter
14 the food supply.

15 In Africa consumption of fumonasin contaminated
16 grain is associated with elevated esophogeo cancer incidents
17 in humans. This microtoxin occurs in the United States in
18 between a half of one percent and 10 percent of the corn
19 acreage yields grain with fuonasins exceeding the
20 recommended safe level for horses. Because there is a close
21 correlation between insect damage and microtoxin
22 concentrations BT corn represents the most effective tactic
23 available for reducing fumonasin and alfa toxin levels in
24 corn prior to harvest.

25 Our research and that of others has shown that

1 insect damage to conventional hybrids leads to elevated
2 fumonasin and alfa toxin levels in the grain. Controlling
3 insect damage through genetic modification with BT prevents
4 this build up of microtoxins. Based on the demonstrated
5 lower microtoxin concentrations in corn it's my opinion that
6 transformation of corn hybrids with BT enhances the safety
7 of grain for use as animal feed or as human food products.
8 This is a consumer benefit already being realized but I
9 think that this is often lost in the outcry over concerns
10 that are less relevant to human and animal health. Thank
11 you.

12 MR. ROBERT LAKE: Thank you, sir. Next.

13 DR. HARRISON J. ROGERS: I'm Harrison Rogers past
14 president of the American Medical Association and a surgeon
15 with 35 years experience in Atlanta. Someone who's worked
16 closely with both the Georgia Department of Health and the
17 Emry [phonetic] School of Medicine.

18 I feel that food biotechnology is essential to the
19 future of public health. In my career I've seen
20 biotechnology supply an endless supply of medical benefits.
21 Doctors have been able to save lives which otherwise would
22 have been lost, families have been strengthened and our
23 nation better because of it. I believe agricultural
24 biotechnology can offer similar improvements by giving
25 doctors and patients tools that maximize their ability to

1 use nutrition to reduce the risk of and perhaps even to
2 resist illness.

3 The American Medical Association has been aware of
4 food biotechnology for years. In 1990 the AMA house
5 received and adopted a report from our Council on Scientific
6 Affairs that had recommendations as follows: First that the
7 report call for the endorsement of a program to ensure the
8 public knows something of biotechnology is not inherently
9 dangerous; Second it requested support for federal
10 guidelines that ensured safety but do not obstruct the
11 development of new products; Third it encouraged state
12 medical societies to coordinate education programs for
13 physicians so they can provide expert advice to their
14 patients; Fourth it encouraged those physicians to be public
15 spokespersons for technologies that can benefit the public
16 health.

17 I'm here today because I believe that the spirit
18 of AMA's position as the council reported is good and I hope
19 that the council will continue to support this sort of
20 education and provide information to the FDA in this area.
21 As a physician it's my duty to protect and serve each of my
22 patients and wherever possible to lend support to those
23 technologies which will further their care. Food technology
24 can do this. Thank you very much.

25 MR. ROBERT LAKE: Thank you, sir. Next.

1 MR. CARROLL BOLEN: I'm Carroll Bolen the Vice
2 President at Pioneer Hibred International. Recently Dupont
3 completed a merger with Pioneer and the combination of
4 Dupont and Pioneer is a major step towards the discovery,
5 development and commercialization of a new generation of
6 products across the value chains for food and feed crops,
7 food ingredients, industrial applications and nutrition
8 science.

9 A key tool in this effort is --

10 MR. ROBERT LAKE: Could we stop one moment?
11 There's some hum in the system, do we know what that is?
12 Can we do anything about that? Maybe what we will do is
13 take a five minute stand up break and we'll see if we can
14 figure out this hum. And I for one could use a stand up
15 break. We'll let you start over again. How about that?
16 All right. Thank you.

17 [Off the record.]

18 MR. ROBERT LAKE: Also, if people could quit
19 talking and so that we can go ahead and get started. And we
20 will let you restart, sir. So go ahead.

21 MR. CARROL BOLEN: Thank you very much, Mr. Lake.
22 My name is Carroll Bolen I'm a Vice President at Pioneer
23 Hibred International. And recently Dupont completed a
24 merger with Pioneer and the combination of the two companies
25 is a major step towards the discovery, development and

1 commercialization of a new generation of products across the
2 value chains for food and feed crops, food ingredients,
3 industrial applications and nutrition science.

4 A key tool in this effort is the utilization of
5 biotechnology which we feel has the potential to lower the
6 environmental impact of society on the planet while
7 enhancing the quality of life for a broader percentage of
8 the world's population. Dupont and Pioneer believe this
9 tool allows us to reliably and safely increase the
10 productivity of the land which reduced the need to bring
11 fragile or forested lands into food production.

12 This technology gives farmers, regardless of size
13 of their operation, the potential to increase their
14 productivity and profitability by growing crops with
15 specialized value added traits and resistance to pests.
16 We're fully committed to this science although it is only
17 one of a number of tools we are using to bring benefits to
18 consumers. Clearly the future benefits of the technology
19 are enormous yet we are aren't pursuing this technology
20 blindly either.

21 We believe the U.S. regulatory framework between
22 the EPA, USDA and FDA has a very successful history of
23 providing the world's most abundant, safest and most
24 affordable food supply. Your statement of policy, foods
25 derived from new plant varieties provides Pioneer with the

1 guidance, oversight and consultation necessary to ensure the
2 products we develop meet the safety standards of the Food,
3 Drug and Cosmetic Act. Further the FDA's decision to keep
4 the policy that governs the evaluation and regulation of
5 bio-engineered foods flexible allows the safe use of emerging
6 biotechnology techniques while continuing to ensure the
7 safety of new foods.

8 Pioneer's experience with the Brazil nut protein
9 is a good example of how the FDA guidance assists company's
10 work to ensure consumer safety when they develop and test
11 new products. In 1993 we discontinued our research program
12 aimed at enhancing methionine [phonetic] content of
13 soybeans.

14 MR. ROBERT LAKE: Thank you, sir. Go ahead ma'am.

15 MS. CISSY BOWMAN: Hello. My name is Cissy Bowman
16 and I'm not a professional activist I want to make that
17 clear. I'm a certified organic farmer. I'm also the Vice
18 President of the Organic Farmers Marketing Association,
19 which is an international organization. I am the chairman
20 of the Indiana Organic Peer Review Panel, I'm appointed by
21 the governor of the state of Indiana. And I'm a
22 grandmother.

23 I heard earlier that there was concern that
24 labelling GMO foods might stigmatize these foods. That's
25 what they said about organics 10 years ago. People haven't

1 quit buying conventional food, however, organics is not a 4.
2 billion dollar industry. Well perhaps you'd say let people
3 then that want GMO free food eat organic but there's a
4 problem with that and it's called drift.

5 GMO pollen get in dust, gets in the wind, on the
6 legs of insects, gets in the water and it can contaminate
7 our crops rendering them no longer certifiable organic. It
8 can literally put me out of business in just one breeze. I
9 don't know how we're supposed to protect ourselves. Earlier
10 you asked about what type of labelling wouldn't be
11 misleading. Maybe you could look at organic labelling
12 regulation as in the Organic Foods Production Act as some
13 potential models, define genetically engineered, use a
14 tiered labelling system, maybe may contain GMOs, made with
15 GMOs and GMO free.

16 Look at an ISO 65 based requirements for
17 certification bodies type of a quality assurance protocol as
18 opposed to quantitative analysis. This is just food for
19 thought but thinks that you asked for earlier. I thought
20 maybe you could use the system that we've set up in organic
21 regulation to maybe inspire you a little bit. It really
22 frightens me to hear someone say that they don't think that
23 we can have zero GMOs anymore. It will be too late for
24 organic farmers certainly unless there's something that can
25 be done now.

1 Who will be liable when my crops get contaminated
2 with GMOs? What do I do? We asked USDA they said it would
3 be treated the same as any other pesticide residue drifting
4 on us but there's no precedent set, there's really nothing
5 that we can do. Finally as a grandmother with a lactose
6 intolerant grandson it scares me to death that he's one of
7 the guinea pigs that's going to be raised on genetically
8 modified soybean formula. Thank you.

9 MR. ROBERT LAKE: Thank you, ma'am. Next.

10 MS. BARBARA MCLARKEY: My name is Barbara
11 Alexander Mallarkey [phonetic] whose name was spelled wrong
12 in the program. I ask FDA to modify their policies and
13 procedures and ban production of genetically engineered
14 seeds and plants. They have the potential to disrupt the
15 fragile fabric of our lives. As a mother, grandmother,
16 President of Nutravoice [phonetic], spokeswoman for the
17 Illinois Vaccine Awareness Coalition and a journalist I am
18 concerned about genetically engineered foods and vaccines.

19 An organic farmer recently said GE technology, a
20 pandora's box, is about the ownership of life itself. If
21 patent protection was removed from a live, invasive alien GE
22 organisms the industry would evaporate like the morning dew.
23 Can humanity afford GE technology's risk of a mistake with
24 irreversible consequences? FDA aspartame approval paved the
25 way for GE bovine growth hormone and subsequently GE seeds

1 and plants. Politics won out over sound science and FDA
2 approved aspartame.

3 FDA continues to deny access to aspartame's
4 complaints statistics. As a newspaper columnist FDA denied
5 me a 1989 key 180-day serul [phonetic] study on GE bovine
6 growth hormone. The last line of its reference in science
7 states "and all gross lesions for 360 rats". Although FDA
8 usually releases studies after approval of a product or
9 process denial was based on trade secret provisions. On
10 appeal, HHS upheld the denial. Genetically engineered seeds
11 and plants followed.

12 If FDA had a policy which funnelled manufacturer's
13 testing money to independent scientists we wouldn't be here
14 today. If FDA had paid attention to FDA toxicologist Dr.
15 Jacquelyn Varet [phonetic] and Dr. Adrian Gross aspartame
16 and its GE followers wouldn't have made it to market. If
17 FDA had ethical hiring practices their officials would have
18 rejected hiring Monsanto affiliated Michael Taylor, Margaret
19 Miller and Susan Sassion [phonetic] to work on bovine growth
20 hormone. Thank you.

21 MR. ROBERT LAKE: Thank you.

22 MR. LEON CORIZINE: Good afternoon. My name is
23 Leon Corizine, I'm a grain and livestock producer from
24 Assumption in Christian County. I also serve as Vice
25 President of the Illinois Corn Growers Association. Let me

1 start off by noting ICGA recognizes the safety, benefits and
2 future potential of biotechnology. However, with the
3 introduction of bio-engineering we have ventured into a new
4 era.

5 Given the emotion and sometimes irrational
6 response to genetically modified food ingredients ICGA
7 believes that it's time for FDA to reassess its current
8 system and potentially expand its roll. ICGA would like to
9 see FDA, the USDA and the EPA expand their traditional rolls
10 to encompassing increased public outreach on biotechnology.
11 As the public is bombarded with mixed messages on
12 biotechnology is it increasingly important they understand
13 how these products are reviewed and tested rigorously prior
14 to reaching supermarket shelves.

15 FDA needs to be in the lead in setting standards
16 and tolerances. This should be pursued aggressively and as
17 soon as possible to ensure continued public confidence. We
18 need to look beyond the agronomic benefits of this
19 technology for farmers today and let consumers know what it
20 will mean for them in the near term and in the year ahead.
21 Today we have the environmental benefits of reduced
22 pesticide application, on the nutrition front grain quality
23 is better with few microtoxins. Ultimately, consumers will
24 see human health and pharmaceutical applications such as
25 edible vaccines.

1 We must be more diligent in the future to assure
2 regulatory acceptance of biotech products prior to
3 commercial introduction. Illinois Corn Producers, for
4 example, export 45 percent of their production so exports
5 are important to us. ICGA also believes FDA should
6 facilitate the introduction of a voluntary labelling system
7 to identify GMO free products. However such labelling
8 should continue to be science based. Strict guidelines for
9 truth and labelling will also be necessary or the marketing
10 gimmicks may escalate confusion over biotechnology and erode
11 the public confidence.

12 If handled properly biotechnology will also allow
13 U.S. consumers to continue to have the most abundant high
14 quality food supply of any nation in the world. Thanks.

15 MR. ROBERT LAKE: Thank you, sir. Yes, ma'am. Go
16 ahead.

17 MS. ROBERTA MCCALLEB: Thank you for giving me the
18 opportunity to speak. I'm Roberta Mccalleg and I represent
19 Access Living's Organizing Project for People with
20 Disabilities West Side DAWN. DAWN stands for disabled
21 Americans working now. And I want to talk to you about
22 preserving safe, healthy and affordable food options for
23 everyone.

24 We take it for granted that we live in a country
25 that offers us abundant healthy food at reasonable prices.

1 What happens if tomorrow all that changes because biotech
2 foods face strict regulations? Will I be forced to buy
3 organic foods when traditional foods disappear because of
4 misguided consumer fears? Many people within my age group
5 live on fixed incomes. Organic foods, especially produce,
6 are incredibly expensive and sometimes cost twice the amount
7 of non-organic foods.

8 If biotechnology critics of their way and biotech
9 foods are cleared from supermarket shelves how will
10 consumers be able to buy the nutritional food they need and
11 stay within their budgets? I don't think many of America's
12 families can afford to double their monthly grocery bill, I
13 know I can't. For decades research has linked healthy food
14 living with healthy eating. In addition to being affordable
15 biotech foods have the ability to increase food's nutrient
16 and vitamin contents and in the future reduce the amount of
17 saturated fat thereby improving our health and well being.

18 To many seniors the increased risk of medical
19 conditions such as osteoporosis and heart disease are real.
20 Foods with the enhanced nutritional value and lower
21 saturated fats can help all of us fight the battle to stay
22 healthy. Biotech foods feeds millions of people. We must
23 encourage their growth rather than destroy their chances for
24 success. Why would we want to disrupt our food sources
25 without any signs of evidence that there is anything wrong

1 with it? Thank you.

2 MR. ROBERT LAKE: Thank you, ma'am. Yes, sir.

3 MR. RYLAND UTLAUT: Thank you, Dr. Henney and
4 distinguished panelist. My family and I grow corn and
5 soybeans in Missouri. Now I am Ryland Utlaut, past
6 president of the National Corn Growers Association of 30,000
7 corn growers. Approximately one third of our country's 72
8 million acres of corn were planted with biotech seed last
9 year. Consequently, corn farmers have a tremendous stake in
10 this new technology.

11 When a farmer plants a crop we deal with the
12 uncertainties of weather and commodity prices. That's the
13 nature of our business. However, no farmer should have to
14 question whether they will have a market for the crop they
15 produce. That is why the determinations of the FDA are so
16 critically important. Farmers need to know that the grain
17 they produce is suitable for its intended use as food or
18 feed and consumers must be able to purchase U.S. food
19 products with complete confidence.

20 I've grown biotech varieties of corn and soybeans
21 for three years. I am comfortable with the science behind
22 the technology and the safety of the technology. However,
23 despite all of my confidence in the products and my
24 stewardship of this technology I'm not a scientist.
25 Scientific assurance of safety must come from the FDA and

1 other regulators. Both the science at the disposal of the
2 FDA and the process that accompanies their science based
3 regulations is vitally important to assuring consumers of
4 the safety of these products.

5 We believe the U.S. experience with biotech
6 products should give both farmers and consumers confidence
7 in the U.S. regulatory process. Reviewing the procedures
8 currently used by the FDA and this hearing as well as the
9 two that follow should lead to greater confidence on the
10 part of all. Greater confidence can only lead to more
11 opportunity for both consumers and producers. Thank you on
12 behalf of the National Corn Growers.

13 MR. ROBERT LAKE: Thank you, sir. Next.

14 MR. JACK HURLEY: Ladies and gentleman of the
15 panel, my name is Jack Hurley and I'm a member of Teamsters
16 Local 726. We represent 5,300 workers in Illinois. And I'm
17 here to tell you how important your actions today concerning
18 biotechnology regulations are to the men and women I work
19 with and over a million Teamsters all over the United
20 States.

21 Many of my fellow Teamsters deal mainly with
22 shipments in the farming and food industry. What all the
23 critics are talking about here today could have severe
24 ramifications for my friends and coworkers. We're talking
25 about thousands of jobs that depend upon the thriving food

1 industry in this country. We should not take for granted
2 the growing food industry in this country of the plentiful
3 and affordable food it provides to us each day. If you
4 place misguided restrictions on all biotech foods to satisfy
5 a few you could hurt countless food industry workers and
6 consumers.

7 If farmers and food producers are forced to place
8 additional labels on biotech foods it would be like putting
9 a skull and crossbar on each product. The end result would
10 be that consumers will shy away from these foods for no
11 other reason than that a label that implies risk. Each time
12 a consumer walks away from a biotech product food industry
13 jobs and working families are in jeopardy. Everybody in the
14 food industry depends upon one another; the producer,
15 manufacturer, distributor and ultimately the customer.

16 When one person in the industry suffers it
17 trickles down to all of us. By attacking food companies
18 through unnecessary regulation everyone in the food industry
19 business would pay the price and for some working families
20 that would be a hard price to pay. Thank you.

21 MR. ROBERT LAKE: Thank you, sir. Next.

22 MR. DANIEL MAINGI: My name is Daniel Maingi, I'm
23 from Kenya. I represent the Kenya Agricultural Research
24 Institute. Let me begin by making a comment that the
25 comments we make here and the way the press presents this to

1 the public has a great repercussion not only in the U.S. but
2 all over the world and let's do it from well informed,
3 knowledge based.

4 Agriculture in the U.S. and most of the developed
5 world is more based on quality improvements. What is in
6 Africa we are really dealing with quantities because we want
7 to feed an ever raising population. And I remember, for
8 example, when I was young we were very busy with my
9 grandmother cultivating large pieces of land so that we
10 could plant corn that would yield so little. And I became a
11 plant breeder. I had the chance of working with the
12 International Potato Center where we developed -- resistant
13 potatoes.

14 And fortunately after 10 years of evolution this
15 finally were very high yielding resistant but they had very
16 high -- levels which you find only late in the season. Now,
17 the problem is that it's very slow when you're dealing with
18 traditional breeding. It takes a number of years. Then
19 you're also changing a large number of genes and physiology.
20 Also, you increase the level of safety because of these
21 changes.

22 Now when you go to biotechnology you are targeting
23 one or two genes which is very precise and can elevate back
24 and forth until you are very sure before you can release
25 these products to the public. So biotechnology for us in

1 the developing world offers the best potential for feeding
2 and ever increasing population. Thank you.

3 MR. ROBERT LAKE: Thank you, sir. Next.

4 MR. EARL NESTMAN: I'm Earl Nestman from Cantox
5 Health Sciences International. These comments are provided
6 from a scientific perspective on food safety, a specialty of
7 our toxicology and regulatory sciences company. As
8 Canadians we also offer our international perspective from
9 our participation in several working groups namely the World
10 Health Organization and the International Food Biotechnology
11 Council that developed guidelines and procedures for the
12 safety assessment of genetically modified foods.

13 Our first observation based on our initial
14 examination of the FDA's '92 policy and subsequently on our
15 review of the outcomes of many FDA consultations is that
16 this process is consistent with scientific principles that
17 have been developed by international groups of experts.
18 These principles provide a framework and guidance for the
19 molecular, biological and chemical characterization of food
20 products derived through gene technology.

21 Secondly an important feature of the '92 policy is
22 it's basis in a standard of safety that has relevance,
23 scientific validity as well as common sense. That is
24 substantial equivalence to traditional foods that are
25 considered safe today.

1 Third we know that the consultative approach
2 allows for the strongest science available. Because the
3 interactive process is flexible it can readily adapt both to
4 contemporary innovations in biotechnology and to
5 developments in safety testing and assessment. Therefore,
6 in the context of the three questions posed for discussion
7 of scientific and safety issues.

8 One, the current FDA policy is achieved its
9 purposed and is poised to continue to fulfill the purpose of
10 ensuring safety of genetically engineered foods. The
11 inherent flexibility can readily capitalize on any possible
12 innovations in characterization, testing and safety
13 assessment. And last, this flexible approach, likewise, can
14 continue to accommodate any future types of food products
15 with the ultimate safety net of imposing requirements of an
16 alternate pre-market approval process when satisfactory
17 answers cannot be supplied for whatever the reason. Thank
18 you.

19 MR. ROBERT LAKE: Thank you, sir. Next.

20 MS. MARJORIE FAUST: I'm Marjorie Faust an
21 associate professor at Iowa State University. And I
22 personally have conducted research investigating the safety
23 and nutritional equivalence of BT corn for livestock.

24 In 1996 we conducted a trial to access whether
25 milk contains BT proteins when high producing dairy cows are

1 fed transgenic BT and non-BT genetic control plants. Our
2 study findings indicated that transgenic proteins were not
3 detected in milk samples from cows fed the steady diets.
4 Moreover, high producing dairy cows, including those used in
5 our study, are very sensitive barometers for many seemingly
6 small nutritional differences that may occur.

7 However, we found no statistically important diet
8 group differences for milk yield components, feed intake,
9 milk composition and utter health of cows in our study. To
10 investigate composition for BT corn hybrids during 1998 we
11 used whole plant samples from BT and respective non-BT
12 genetic counterparts from midwestern states. Silage
13 [phonetic] and fresh frozen whole plant samples were also
14 evaluated for nutritional composition by an independent
15 laboratory and our findings suggest similar feeding values
16 for BT and non-BT counterparts based on results for more
17 than 15 important feeding related nutrients during all
18 phases of a traditional typical corn silage harvest
19 maturity.

20 Results from our studies as well as those from
21 other universities coaberate the safety and equivalence of
22 transgenic crops as livestock feeds as documented initially
23 by the governmental approval process. Based on my
24 professional experience with commercial transgenic crops I
25 recommend that approval for biotechnology products continue

1 to be based on scientific principles and results. Thank
2 you.

3 MR. ROBERT LAKE: Thank you, ma'am. Go ahead,
4 sir.

5 MR. JOHN BESKE: Good afternoon. My name is John
6 Beske and I'm a Chicago based vegetarian activist and an
7 active member of several environmental and vegetarian groups
8 and one of more than 15 million vegetarians in the United
9 States. So far the debate concerning genetically engineered
10 foods, beyond the fact that it has been highly controlled by
11 the millions of dollars and highly paid experts, lobbyists
12 and propaganda of the biotech industry, beyond that the
13 debate is centered almost entirely on one subject, food
14 safety.

15 You're hearing a lot of testimony declaring these
16 products as safe and a lot of other testimony saying that it
17 might not be. I want to say that even if we know
18 unequivocally if every single GE product is safe, and I
19 personally can't see that happening, there are still a great
20 number of reasons to oppose them. Particularly when we
21 place animal genes in plant foods. It is, at the very
22 least, essential that all of these products are explicitly
23 labelled so that vegetarians like myself will know to avoid
24 them.

25 It is critically important for the FDA to

1 understand that a great number of Americans are opposed to
2 genetically engineered foods for purely ethical reasons and
3 that we need to be able to have access to a wide variety of
4 foods that are free of genetically modified organisms.

5 Thank you very much.

6 MR. ROBERT LAKE: Thank you, sir. Go ahead ma'am.

7 MS. MELINDA PERRIN: Thank you for expanding this
8 hearing so that more voices can be heard. I appreciate the
9 opportunity that has been granted. I'm Melinda Perrin and I
10 stand before you one voice but I represent many: The Seneca
11 [phonetic] Indian Historical Society, The Prairie Earth
12 Unitarian Universalist Fellowship, the Seneca Indian Wolf
13 Clan Teaching Lodge and over 380 people who have contacted
14 me directly this past week because they could not be here.

15 I am/we are opposed to genetically altered food
16 crops for many reasons but bio-ethics aside we'll present
17 two simple arguments. First that like DDT genetically
18 engineered crops might seem initially to be a panacea
19 [phonetic] but may prove to be deadly in the long term.
20 Unlike DDT the problems once unleashed can never be called
21 back. This argument can best be stated in the Native
22 American philosophy "Do nothing without considering the
23 effect on the next seven generations." In this case it can
24 be taken literally.

25 Genetic alterations effect both the seed and the

1 pollen. It is virtually impossible to guarantee that cross
2 pollination into non-genetically altered plants will not
3 happen. Pollination whether by wind, insects or other means
4 is not easily controlled. Genetically engineered food crops
5 already threaten beleaguered heritage seeds in this country
6 including the traditional sacred white corn of the Iroquois
7 people.

8 I can choose to consume organic food or not, but
9 currently I cannot choose to consume non-genetically altered
10 food. I can choose to grow genetically altered plants, but
11 if not how can I guarantee that my crop is genetically pure
12 if my neighboring farmer is using genetically engineered
13 seed? Consumers deserve the right to shun such produce and
14 the processed foods made with them, but we are not given a
15 choice. Please stop genetically engineered food crops in
16 the United States and the importation of such products. At
17 the very least please require the labelling of all such
18 produce and the processed food made from them. Thank you.

19 MR. ROBERT LAKE: Thank you, ma'am. Go ahead sir.

20 MR. JOE WHITE: My name is Joe White. I'm a
21 farmer and I'm proud of it. I've been farming for 24 years
22 and currently manage 950 acres of corn, soybeans, wheat and
23 hay. I'm here today as a farmer and also for a spokesperson
24 for the Illinois Farm Bureau.

25 Our farmer members support biotechnology and

1 biotech research to address environmental concerns, improve
2 product markets, enhance the competitiveness of U.S.
3 agriculture and to ensure all consumers a stable, plentiful,
4 safe and nutritious food supply. The current FDA review
5 process is fair and accurate in determining the safety of
6 food derived from bio-engineered plants. This process
7 ensures that all consumers are receiving the safest food
8 supply in the world. We firmly believe increased
9 educational efforts regarding the safety and effectiveness
10 of biotech products is essential to improving knowledge
11 about and acceptance of these products.

12 This information can best be distributed through
13 the use of the internet and traditional publications. Farm
14 Bureau does currently and will continue to inform its
15 members and the public on all aspects of food production.
16 Labelling would be an important aspect of this education and
17 information sharing. Illinois farmers support proper
18 labelling of food and other agricultural products and we
19 fully support the science based labelling policies of the
20 FDA.

21 We are generally supportive of voluntary labelling
22 of identity preserved agricultural products based on clear
23 and factual certification process that results in a value
24 added return to the producer. For two years I have used and
25 planted BT corn and I've used and planted Round Up Ready and

1 STS soybean varieties. I plan on continuing to use this
2 technology.

3 My number one reason for using this technology is
4 because it's safe. It's safe for me as the individual
5 producer it's safe to the environment and it's safe for the
6 consumer. Future technology will improve products requiring
7 fewer crop protectants and will very likely improve the
8 nutritional or functional characteristics of those products.
9 This technology is essential for U.S. agriculture to remain
10 competitive in a global economy and supply the food needs of
11 the world into the next millennium. Thank you.

12 MR. ROBERT LAKE: Thank you, sir. Next.

13 DR. JERRY HJELLE: Yes. My name is Jerry Hjelle,
14 I'm Vice President of Regulatory Affairs with the Monsanto
15 Company. I would like to thank the FDA for holding these
16 public meetings to share information and encourage public
17 dialogue and I appreciate the opportunity to speak.

18 Monsanto has conducted research and development in
19 agriculture biotechnology for the better part of the last
20 two decades. We've worked to develop and commercialize
21 products that help farmers manager plant pests and diseases.
22 The use of insect protectant and herbicide tolerant crops by
23 farmers has helped reduce pesticide usage, lessen soil
24 erosion through conservation tillage, improve food and feed
25 quality and lower food production costs. Important benefits

1 for the environment and consumers.

2 In the near future researchers will develop
3 products with enhanced nutritional and quality traits and
4 scientists are also working to improve crop productivity in
5 developing countries. FDA's implementation of the 1992
6 policy for new plant varieties has been effective. The
7 policy itself is science based and provides adequate
8 guidance. It addresses relevant questions for new products
9 and methods and FDA assures that appropriate safety
10 questions are addressed or resolved during the consultation.

11 We are committed to developing safe and nutritious
12 products for farmers, food companies and consumers. The
13 reviews done by FDA together with those done by USDA and EPA
14 are critical to building public trust in the safety of new
15 products. Prior to FDA review comprehensive research
16 studies are done to evaluate the composition, nutrition and
17 safety of these crops. We have an will continue to seek
18 FDA's review of our biotechnology products and will address
19 and resolve all issues before any product is sold
20 commercially.

21 We are also committed to communicating information
22 and obtaining feedbacks about our products. Our internet
23 website at www.monsanto.com provides links to hundreds of
24 independent sources as well as access to over 10,000
25 articles and reports related to our products and

1 biotechnology. We have had over two million visitors
2 accessing information on this site.

3 MR. ROBERT LAKE: Thank you, sir.

4 DR. JERRY HJELLE: Thank you.

5 MR. ROBERT LAKE: Go ahead ma'am.

6 MS. WENDY ALLEN AIRES: My name is Wendy Allen
7 Aires. I'm an anthropologist. I follow with the tradition
8 of the chair of the anthropology department of the
9 University of Chicago, Saul Tax [phonetic], who founded the
10 school of action anthropology. My thing, my endeavor is
11 called multilog. We do politic market and operations
12 research. We also publish t-shirts, for example, believe it
13 or not, to legalize marijuana.

14 Now, one of the problems I discovered this morning
15 in talking to the assistant commissioner is that the FDA is
16 concerned primarily with food safety. They do not have the
17 authority to protect the environment. We've heard today of
18 the various genes that are floating in our food supply which
19 may or may not be dangerous to some people not the majority.

20 What we have not focused upon, and I want to quote
21 a earlier speaker here Mr. Robert Haselkorn the professor
22 from the University of Chicago. He told me in questioning
23 after this session that the solution to these wild genes,
24 these poison genes, these lethal genes to microbes and he
25 says, "After all, we got all these genes from microbes in

1 the first place", is not to stop using them but to
2 incorporate ever more lethal genes from the microbes to wipe
3 out the various organisms in the soil and the insects.

4 This is ecocide [phonetic]. This is destroying
5 the fabric of our ecology. Drifting from the fields and
6 threatening the organic farmers and causing them actual
7 economic harm is a dispersion of these mini genes into all
8 sorts of species. Lately we found out that it kills monarch
9 butterflies.

10 MR. ROBERT LAKE: Thank you, ma'am. Next.

11 MS. WENDY ALLEN AIRES: The answer is not all or
12 nothing but a case by case basis.

13 MR. ROBERT LAKE: Next.

14 MR. MARK KNAPP: Hello my name is Mark Knapp. I
15 am a radiological health scientist and I've travelled from
16 Minneapolis to be here today. I would have liked to have
17 attended such a public meeting in my own state but I
18 understand the agency's limited resources and wide overall
19 public health responsibility. Judging by the recent rash of
20 Monsanto tv advertising I also understand the biotechnology
21 seemingly endless resources when huge profits and power are
22 at stake. They have no problem putting a corporate hit team
23 on a last minute airplane in first class to any location.

24 Having said that, I would like to thank the FDA
25 for so graciously allowing me to take 120 seconds of its

1 time. I'm sure the agency members would rather be busy
2 extending their relationships with biotechnology promoters
3 to set themselves up with lucrative industry employment
4 after government service. I'm glad to take away some of
5 that time. To be in this room I had to surrender my Fourth
6 Amendment Right to be free from search or seizure without
7 prior suspicion. My body and my belongings were searched
8 with electromagnetic fields.

9 However, at least some of the Bill of Rights is
10 left. And in particular our democracy is alive whether the
11 biotechnology industry likes it or not. The contempt that
12 biotech companies and the FDA seem to have for democracy
13 reminds me of my 14 years of experience with the nuclear
14 industry and the Department of Energy. If I had the time
15 I'd go into that. The fundamental currency of democracy is
16 the truth. Not labelling engineered food is therefore an
17 attack on democracy.

18 I'm appalled that there is even a consideration of
19 not providing clear, concise, non-biased wording on food
20 labels and it's really not that difficult.

21 Proponents of GE Food claim that there is no
22 substantial difference between biotech food and organic
23 food. If this were true then why does the U.S. Patent
24 Office issue patents for genetically engineered food?
25 Finally, the tampering with the genetic code of life reminds

1 me of the sorcerers apprentice. Ten years ago George
2 Leonard, the Associate Chief of the U.S. Forest Service,
3 spoke about replacing forests with tree plantations. His
4 statement bears repeating in this forum. He said, "We know
5 what nature can do and we're relatively certain that we can
6 do better than nature." That's arrogance.

7 MR. ROBERT LAKE: Thank you, sir.

8 [Applause.]

9 MR. ROBERT LAKE: Yes, ma'am. Go ahead.

10 MS. MARJORIE FISHER: I'm Marjorie Fisher and I'm
11 speaking for the League of Women Voters. I wish to make two
12 points. First of all the League has national position a
13 very strong position on citizens right to know. So, my
14 first point has to do with labelling. In other words, we
15 would want to have the food or any products, the
16 manufactured products labelled that either it is genetically
17 engineered or contains genetically engineered material. And
18 that would be straight forward.

19 I do recognize the major point of drift. I think
20 in the case of the organic farmers movement we certify
21 people has having not used it in the first place and that is
22 what we want to do. We want people to be able to certify
23 that they have not used the genetically engineered and I
24 want the FDA to support that and support enforcement.
25 That's the first point.

1 The second point is very specific. The League of
2 Women Voters has a national position on pesticides. It says
3 that we wish to reduce the exposure of everyone and we want
4 them to use non-toxic alternatives. And we can give you
5 many examples of exactly how to do this. And in this I
6 mention Monsanto's Round Up, specifically made so that more
7 pesticides can be used and I have two pieces of information
8 for you and everyone can pick them up themselves.

9 MR. ROBERT LAKE: Yes. And you may submit those
10 for the record as well.

11 MS. MARJORIE FISHER: Yes. And breaking the cycle
12 of violence is one.

13 MR. ROBERT LAKE: Thank you, ma'am. Okay. Go
14 ahead sir.

15 [Applause.]

16 MR. DAVID DEROSA: Hello. My name is David
17 DeRosa. I'm not speaking today representing Greenpeace of
18 Consumers Union or any of the other groups that have already
19 spoken here today, although I am a member of them. I wanted
20 to speak more to the FDA's process. I think we've heard a
21 lot of people today speaking against genetic engineering for
22 many many reasons some crazy, some very sensible, all
23 honest. And all of the biotech industry people speaking in
24 favor of it all for exactly the same reason which is that
25 they think we should just shut up and sit down and let the

1 experts do what's best.

2 And that really is what concerns me about the FDA.
3 This hearing has been seven years overdue and then was
4 rushed quite quickly to the point where a lot of the public
5 couldn't get involved and all of the paid experts, people
6 who had their money on the line were here instead. Seeing
7 Mike Phillips on a panel who just went through the revolving
8 door from the National Academy of Sciences to the
9 bio-industry is a perversion of any public hearing and
10 shouldn't be allowed to speak for years about any of these
11 issues having abused his government privilege in that way.

12 This meeting from what I can see is not really
13 about science, ethics, education or any other high fluent
14 abstraction. It is fittingly enough on the eve of the
15 Seattle WTO meeting about the rush to make money in the
16 inexorable poll of the positive quarterly return. Genetic
17 manipulation does hold promise. It's use alone won't feed
18 the world but it could make agriculture possible in
19 previously unusable lands in other true advances. It could
20 also, as we've heard, go terribly wrong in myriad ways.

21 So my question for both the biotech industry in
22 general and for those who planned this meeting in particular
23 is what's the rush? If these things are really going to
24 make our lives better, if they're going to create benefits
25 for the consumer then people will want to see them labelled

1 and the industry will want to label them. Basically, I
2 think we must slow down the cutting edge of technology or we
3 will cut out our brains to spite our face values.

4 [Applause.]

5 MR. ROBERT LAKE: Thank you, sir. Next. Go ahead
6 sir.

7 DR. BILL VONMYER: My name is Dr. Bill Vonmyer, I
8 am President of Fairview Industries former Vice President of
9 the largest genetic engineering company in the world.

10 References in Data Today are released for the
11 first time in the United States showing that -- this is this
12 report -- bovine growth hormone is tested in 1965 promoted
13 diabetes in diabetic patients. The bovine growth hormone
14 had previously been digested employing trypsin thus it was
15 fragments that did it. Milk from BGH treated cows may
16 contain increased cow serum protein following injection.
17 This was reported in a journal Dairy Science. Antibodies to
18 cow serum proteins have now been found associated with the
19 induction of childhood diabetes in European research on
20 human.

21 A congressional inquiry by the office of the
22 former representative Scott Kloog [phonetic] showed that
23 neither BGH milk or BGH itself were tested in any chronic
24 exposure studies for their ability to induce or affect
25 diabetes and cancer. In fact, milk from BGH cows was not

1 health tested, not fed to any animals in any health test in
2 the United States, even one experiment prior to its approval
3 by FDA. This investigation was conducted by the writer and
4 FDA officials were interviewed in detail about the omissions
5 of critical data on July 2nd, 1998 in the office of
6 Congressman Scott Kloog.

7 Examples of protein enzymes involved in diabetes
8 induction of an auto-immune type were discussed in this
9 report. Recently a WHO review of BGH omitted entirely the
10 potentially adverse affects of BGH milk on liver as reported
11 in a Journal of Nutrition 12514. Why? In general the
12 omission of chronic health testing --

13 MR. ROBERT LAKE: Thank you, sir.

14 DR. BILL VONMYER: Thank you.

15 MR. ROBERT LAKE: Go ahead, ma'am.

16 MS. KATHLEEN CUMMINGS: Good afternoon. I'm
17 Kathleen J. Cummings, President of Milk Outreach
18 Organization Incorporated also known as MOO which was
19 started around the issue of RBGH.

20 I am here to say that we've already opened
21 pandora's box with genetically modified organisms. We must
22 label GMOs. We must give American consumers confidence that
23 they are not being used as guinea pigs. I have three points
24 to make. The first one is for us to consider the affects
25 that other experiments have had on the public and the

1 environment. DDT, DES and philitomide [phonetic] were all
2 used only later to be found to cause devastating problems.

3 Secondly, consumer trust. There are still so many
4 questionable safety issues surrounding RBGH. The FDA
5 withholding research on what happened to the rats but
6 approving RBGH makes it hard for people to know what is safe
7 to eat. How many people have allergies? Then you know how
8 important it is to know what you are allergic to and what to
9 avoid. I am a teacher and I see that asthma, diabetes and
10 hyper activity are on the rise in children. We just don't
11 know what the long term affects of a diet of GMOs are going
12 to create.

13 And thirdly, I have to ask myself why is there
14 opposition to labelling? Why not label as easily as we
15 label wines or clothes? Why not label what we put into our
16 bodies? In closing, we have a right to know what we are
17 putting in our bodies. We need to label genetically
18 modified organisms.

19 MR. ROBERT LAKE: Thank you, ma'am. Go ahead sir.

20 DR. STEVE FULMER: I'm Dr. Fulmer from Indiana.
21 I'm an independent consumer advocate. Over the last eight
22 years I've spoke at high schools, colleges, private
23 organizations, profit organizations, non-profit all over the
24 state of Indiana, Ohio and Illinois. And I would like to,
25 you know, talk to the board today and tell them during that

1 period of time talking to thousands and thousands of people
2 not one person has ever come to me and said that there is no
3 need to label these genetic engineered products. Not one
4 out of the thousands of people that I have talked to, not
5 one.

6 During this period of time I have found that the
7 public once told about the genetic engineering think there
8 are positives and negatives to genetic engineering, of
9 course, of all technology. But the public has a right to
10 know. And the minimum we do today should be that we should
11 label, honestly label all genetic engineered products and
12 the future will bring to us more social problems. This is
13 probably the most dangerous, in my opinion, the most
14 dangerous technology that's ever came along the pipe.

15 It is the new technology that's on fire. It is on
16 fire. It can go so many directions and yet we have no
17 parameters, no guidelines in which way this goes. This
18 could help the human race or destroy it very easily and we
19 all know this. People that are in the business know this.
20 I come to you today I -- my paycheck is I have no paycheck.
21 I am an independent person. I speak because it's out of my
22 heart. And I ask this board today to make sure that this
23 labelling goes in effect immediately or as soon as possible.
24 Thank you.

25 [Applause.]

1 MR. ROBERT LAKE: Thank you sir. Go ahead. Go
2 ahead ma'am.

3 MS. CHRISTINE PHILLIPS: I have been asked to
4 speak for Laura Black who is the publisher of this
5 publication the Organic Food Basket, a little Chicago
6 publication, you might want to pick it up sometime. Laura
7 has a subscription of 300 and growing. And this is just to
8 reiterate to you how concerned people are about what they
9 eat and what they put into their bodies.

10 It's a little newsletter but it's reaching a lot
11 of people and she is a voice for an ever increasing number
12 of organic consumers who will not be swayed by FDA
13 compromises and after the fact solicitation of opinion,
14 which this has been. She is dedicated to drawing attention
15 to organic food, how it is produced, why it is important and
16 why GE is its antithesis. I am sure that Laura would want
17 me to emphasize all of those points again and again and
18 again until I was blue in the face. At any rate. Thank you
19 and I appreciate it.

20 MR. ROBERT LAKE: Thank you. Go ahead sir.

21 MR. STEVE MINSKY: My name is Steve Minsky I
22 represent Nutritional Concepts Personal Health Planning and
23 I speak on behalf of my mother and licensed nutritional
24 counselor, master of public health, Bonnie Minsky and our
25 clientele of over 5,000 strong.

1 You asked should the FDA's policy requiring
2 labelling be maintained or modified. Absolutely and
3 definitively modified. Bonnie Minsky has been practicing
4 nutrition in Chicagoland for 15 years believes that up to 75
5 percent of her clientele have a food allergy or food
6 sensitivity. Any bio-engineered food should be labelled.

7 But the question of whether to label GM foods here
8 is undeniably an issue of consumer choice and that's why
9 I'm here. If no one knows the long term affects of GM foods
10 as Dr. Jacobson eluded to bad or good the consumer should
11 choose whether or not they want to consume the products.
12 Have we not learned enough from the cigarette uproar?

13 Speaking for Nutritional Concepts and our clients
14 we demand the right to choose. Specific labelling is the
15 first and most crucial option. Considering only a third of
16 the public is aware that GM foods exist have the labelling
17 policies served the public? I don't think they've served
18 the public. There are 36 total altered fruits and
19 vegetables but I can't count on one hand the amount of times
20 I've seen a label for a GM food. Something is amiss.

21 Should the information be made available to the
22 public about GM foods? Yes, at every level. Use a logo
23 similar to the certified organic sticker we find on fruits
24 and vegetables. On a box or package put a logo like the
25 recycle logo that we see on a package. Within the

1 ingredients it should be specified how a food has been
2 bio-engineered and should list the other foods that have
3 altered it.

4 Now who should be responsible for communicating
5 information? The government and business. One long running
6 15 second PSA with a website and toll free information
7 number would go a long way to informing the public. Now I
8 want to reiterate food labels should be the number one
9 priority.

10 MR. ROBERT LAKE: Thank you, sir. Go ahead ma'am.

11 MS. ERICA DANA: My name is Erica Dana. I am an
12 organic farmer from eastern Iowa. I practice diversified,
13 sustainable agriculture on a small farm in the middle of
14 corporate chemical farming country. My community supported
15 agriculture program had 20 member families this season. I
16 have learned the hard way that buying, eating and especially
17 growing organic food are political acts.

18 Of all the tools I use to grow food this one is
19 the most important. For those of you at the Marriott it says
20 "Organic Farm. Do not spray. Chemical trespass will be
21 prosecuted." I've provided these signs to organic farmers
22 and groups all over this country because herbicide drift is
23 everywhere.

24 We're talking about freedom here so I'd like to
25 quote "We hold these truths to be self evident that all men

1 are created equal, that they are endowed by their creator
2 with certain unalienable rights that among these are life,
3 liberty and the pursuit of happiness. That to secure these
4 rights governments are instituted among men deriving their
5 just powers from the consent of the governed that whenever
6 any form of government becomes destructive to these ends it
7 is the right of the people to alter or to abolish it and to
8 institute new government laying its foundation on such
9 principles and organizing its powers in such form as to them
10 that shall seem most likely to effect their safety and
11 happiness." Emphasis on safety.

12 "Prudence indeed will dictate the governments long
13 established should not be changed for light and transient
14 causes and accordingly, all experience have shown that
15 mankind are more disposed to suffer while evils are
16 sufferable than to right themselves by abolishing the forms
17 to which they are accustomed. But when a long train of abuses
18 and use of patience pursuing invariably the same object
19 events as a design to reduce them under absolute
20 despotism. It is their right, it is their duty to throw
21 off such government and to provide new guards for their
22 future security," or you can learn to grow your own food.

23 [Applause.]

24 MR. ROBERT LAKE: Thank you, ma'am. Go ahead.

25 MS. DEANNA BELZ: My name is DeAnna Belz and

1 although I represent several organizations today I'm here as
2 a mother and a consumer and I have a lot of concerns. Our
3 faith is shaken as we see government agencies promoting the
4 propaganda of the industry as opposed to protecting the
5 average citizens.

6 I was offended by the term, when they discussed
7 the fact that we are confused, that labelling will confuse
8 us. Labelling will not confuse me. I do know the
9 difference between a genetically altered food and one that
10 is not if it is labelled. I will not know that if it's not
11 labelled. And then it is my choice to look it up on
12 internet or whatever other sources there are to find out
13 whether I choose to eat it or not.

14 I was, like I said, I was offended by being told
15 that as a consumer I will be confused by labelling. Give us
16 the information and let us decide whether or not to feed
17 these children -- to feed our children these products. I
18 would urge you to error on the side of caution as opposed to
19 letting the industry tell you how to make this food
20 available to us. And I would ask that you would please stop
21 using our children as guinea pigs.

22 It concerns me what we're feeding our children.
23 As an educators I see children lining up in the hallways
24 taking medication and I wonder why do these children have
25 these problems? I think we need to spend some of our

1 research dollars on what this food is doing to them and not
2 so much on trying to produce genetically altered foods.

3 Thank you.

4 MR. ROBERT LAKE: Thank you, ma'am. Go ahead.

5 MS. KAREN NELSON ROGERS: Okay. I'm Karen Nelson
6 Rogers I belong to a group called South Cook County
7 Environmental Action Coalition. Thank you to the FDA for
8 holding these public hearings today. One concern I have in
9 regards to trusting the FDA to protect the public and be in
10 charge of overseeing this technology is the way this hearing
11 has been handled by the FDA. I have a feeling from watching
12 and partaking in the registration process for the last two
13 weeks for this hearing that the FDA could mess up a two car
14 funeral.

15 I'm also DES sensitized. My mother was given DES
16 in her second trimester of pregnancy and I bear the
17 consequences along with my two daughters now. So I'm very
18 familiar with this. I feel the public wants and needs to be
19 offered a choice in whether or not they wish to consume this
20 bio-engineered products. Having industry provide its own
21 consultation with the FDA and eluding to it being a defacto
22 mandatory consultation is ludicrous. It's comparable to the
23 fox being put in charge of the chicken coop.

24 The public doesn't need assurances from industry
25 that it will police itself it needs a guarantee from the FDA

1 that this technology is and will be safe and we have not
2 received that. Much has been said today of the benefits
3 given to the consumers of this processes both now and in the
4 future. Yet the only real benefit that can be measured is
5 the monetary gain that companies like Monsanto and Novartis
6 are able to reap. The consumer is just a pawn in the
7 process told how and what to think.

8 Well this consumer says no. I don't want to line
9 the pockets of Monsanto and Novartis all the while risking
10 possible future harm to my family. This industry needs to
11 be stopped in its tracks until any doubts about the safety
12 of genetically modified organisms are completely removed.
13 The burden of proof lies with industry to prove it's 100
14 percent safe. I choose not to use my family as guinea pigs.
15 What's the hurry?

16 [Applause.]

17 MR. ROBERT LAKE: Thank you, ma'am. Go ahead.

18 MS. SANDY GREINER: Good evening. My name is
19 Sandy Greiner, I'm a farm wife and partner, a mother and a
20 grandmother. I'm past president of American Agri-Women
21 which is the nation's largest independent farm women's
22 organization. My husband Terry and I farm on a diversified
23 grain and livestock farm in southeast Iowa near Keota
24 [phonetic]. We're the parents of three grown sons who are
25 each involved in the operation in some way. We live on the

1 same corner on the same farm for the last 33 years.

2 I'm also a member of the Iowa legislature having
3 served seven years in both Ag Committee and the
4 Environmental Protection Committee. I served two years as
5 chairman of the Environmental Protection Committee before I
6 moved to chair the Ag and Natural Resources of -- Committee.
7 It's important to my family that you understand why I came
8 here today. I'm here to speak for my family, I'm not here
9 to speak for the legislature or American Agri-Women or
10 anyone else.

11 We are very very concerned that decisions are
12 being made based on emotional sensationalism rather than
13 sound science, common sense and logic. It's unfortunate
14 that I won't be able to give all of my prepared remarks
15 today. I had two pages of things to say that haven't
16 already been said. But I'm going to go to my conclusion
17 first because I think it's important that everyone hears
18 this. This hasn't been said yet today either.

19 At some point in time you panelist are going to
20 have to ask yourselves just how you base your decision and
21 what it's going to be based on and what all the uproar is
22 about. Is it going to be based on science? Can we count on
23 it being based on science? We hope so. The August 6th --

24 MR. ROBERT LAKE: All right. Thank you, ma'am.
25 Go ahead.

1 MS. SONJA KUGLER: Hi. My name is Sonja Kugler,
2 I'm the general manager of Natural Needs here in Chicago. I
3 do consumer education, fund raising, product marketing and
4 organic foods events for the organic products industry. In
5 the last 15 years I've talked to thousands of mainstream
6 American consumers here in Chicago and trust me, they're
7 quite bright. They do want clean, safe food and I think
8 they would be able to read a package in the supermarket.

9 I love this country and the freedom it affords us
10 to pursue our happiness. These freedoms, of course, are
11 guaranteed to us in the Constitution. We all make choices.
12 I made a choice early in life to eat only clean, pure,
13 wholesome food. This consumer demand actually grew a new
14 national movement in America now known as the natural and
15 organic products industry, a multi-billion dollar business
16 that is the fastest growing category of food in the food
17 industry today.

18 I'm a mother of five children 19 'til 7. I choose
19 a meat free kitchen, a kosher kitchen and certified organic
20 foods. Currently there are food production systems in place
21 that guarantee me access to certified organic foods. The
22 USDA is close to giving us a clear national organic standard
23 one that will not include bio-engineered food as acceptable.
24 There is clear and concise labelling on kosher foods.
25 Animal bio-products are always listed on mandatory

1 ingredient lists. I'm glad this is the law. I like knowing
2 what I am putting into my body.

3 Transgenetic crops compromise my freedom to
4 practice my religion. Once animal genes are spliced into
5 plant genes diverse seeds are sown. How will I know which
6 foods contain animal products? Where will altered genetic
7 material go after it enters our body? What will the outcome
8 for nursing mothers be? Are we altering our own genetic
9 material? And who will be held legally responsible for any
10 national ill health consequence?

11 It is my right as a consumer to know what I am
12 purchasing. All foods containing genetically modified
13 organisms must be labelled as such immediately. Please
14 establish a moratorium on genetically altered food now.

15 [Applause.]

16 MR. ROBERT LAKE: Thank you, ma'am. Go ahead.

17 MS. FELICIA WADSWORTH CARR: Hello my name is
18 Felicia Wadsworth Carr. I am founder and final reviewer for
19 Indiana Certified Organic, I'm also a mother and a consumer.
20 I would like to thank you for this opportunity to address
21 the FDA. This is my official first opportunity on this
22 issue to address my feelings on this issue.

23 In the day-to-day operations of running an organic
24 certified operation the issue of GMO products is always an
25 issue. GMOs are regarded as a synthetic prohibited material

1 Audit trailing of seed sources is the primary concern.
2 Overdrift and cross pollination following that.

3 As a consumer and a mother of small children I am
4 outraged at the corruption of the food chain that has
5 occurred because of GMOs. All I ask for is an audit trail
6 and total mandatory disclosure labelling of all GMO
7 products.

8 Consumers are smart enough to read labels if given
9 the information concerning ingredients. I want the right to
10 make that choice but I have to have the information. I am
11 contaminated but the contamination does not have to
12 continue. Please stop the contamination and mandate 100
13 percent disclosure of GMO foods on labels. Thank you.

14 [Applause.]

15 MR. ROBERT LAKE: Thank you, ma'am. Some of the
16 people who are on our list of people who signed up to speak
17 actually did not speak in the order that we have here. Let
18 me at this time ask if there's anyone in the room who signed
19 up to speak who has not in fact had the opportunity if you
20 would now identify yourself or raise your hand we could, you
21 know, allow you to speak at this time.

22 Okay. I guess that's it then. Commissioner.

23 DR. JANE HENNEY: Well we have reached only the
24 end of today's meeting. I think it has been both
25 informative and very productive for this panel who has

1 listened. We are certainly not at the end of this process
2 of listening.

3 As I mentioned before we still have two meetings
4 to go and hope that we receive input also outside this more
5 formal meeting chain as well. I think that I would like to
6 encourage you again, I know some of you had written comments
7 with you or if you have written comments to follow, to
8 please get them into the docket.

9 I want to thank you in particular not only for
10 your attendance and your participation but the courtesies
11 that you have extended to us being here in Chicago and to
12 each other. And I wish you well in your travels home.

13 Thank you.

14 [Whereupon, the hearing was adjourned.]

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16

STATE OF ILLINOIS)
) SS.
COUNTY OF DUPAGE)

I, RITA LANGLEY, depose and say that I am an electronic reporter doing business in the State of Illinois; that I reported verbatim the foregoing proceedings and that the foregoing is a true and correct transcript prepared under my supervision to the best of my knowledge and ability.

Rita Langley
RITA LANGLEY

SUBSCRIBED AND SWORN TO BEFORE
ME THIS 3rd DAY OF December,
A.D. 19 .

Ronald N. LeGrand, Jr.
NOTARY PUBLIC

