FOOD AND DRUG ADMINISTRATION (FDA)

PUBLIC MEETING: AGRICULTURAL BIOTECHNOLOGY EDUCATION AND OUTREACH

Tuesday, November 7, 2017

Omni Charlotte Hotel

132 E. Trade Street

Charlotte, North Carolina 28202

TABLE OF CONTENTS

P R O C E E D I N G S

WELCOME AND OVERVIEW

MR. WALDROP: Good morning, everyone. Thank you all very much for taking the time to join us here this morning. I hope you all at least had a little bit of time to see Charlotte before you got in here and walk around downtown a little bit. It's very beautiful downtown.

So, thank you again very much for joining us this morning. My name is Chris Waldrop. I'll be moderating the public meeting today.

Today we've come together because the U.S. Food and Drug Administration, the U.S. Department of Agriculture, and the U.S. Environmental Protection Agency are pleased to host the first of two public meetings related to the development of an Agricultural Biotechnology Initiative and Education Outreach project.

Following my opening comments, we'll hear a few comments, very brief comments about the federal government's role in agricultural biotechnology. And then we'll move to the public comment portion of the

agenda.

Before we get started, a few housekeeping notes. The restrooms as you exit the auditorium, if you go down the corridor, the restrooms are there on the right, both the men's and women's. If you're hungry or thirsty during the break there are some places to eat and purchase beverages down on the Plaza Level, that's one level below us so you can just take the elevator down there. I think there's a Walgreens and a Starbucks and a Panera, a Chick-Fil-A, so there's lots of places down there if you need a little snack around about ten o'clock.

I hope everybody got a folder when you registered. If you take a look inside that there's an agenda for today, there's also a list of the people who have registered to make public comments as well as a Federal Register notice that was posted when we announced these public meetings. So, there's some good information there about the background of this initiative, as well as if you're interested in making written comments, there's some information in there as well.

A couple of people have asked about Wi-Fi, so if you do have questions about Wi-Fi connections, please see the folks at the registration desk and they can help you get sorted on that. And if you're a member of the press or the media and you have not registered, please do so at the registration desk or let any of the folks that have a blue ribbon on their name tag, let them know. We just want to make sure we know who's covering this so we can get a count there.

If you have any other questions or need assistance while you're here, please do ask any of the folks with the blue ribbon. They're happy to help you, or check with the registration folks and they can get any sort of things sorted that you need. So, housekeeping stuff is done so let's get to the meat of the matter.

Why are we here today? Well, in May of 2017 Congress tasked the Food and Drug Administration, in coordination with the U.S. Department of Agriculture, to provide consumer education and outreach regarding agricultural biotechnology and biotechnology-derived food and animal feed products. Congress asked us to do

that through the publication and distribution of science-based education materials related to the environmental, nutritional, food safety, economic, humanitarian impacts of biotechnology. And this is the language on the slide that came from Congress as part of the appropriations act and kind of lists out those things I just said. That's where the original task came from for this initiative.

So, when I say agricultural biotechnology and when Congress uses the term agricultural biotechnology, we're also talking about other terms such as genetic engineering, genetically engineered food, some people say GMOs. So, I want you all when you hear us say agricultural biotechnology, to think in those terms if those terms are more comfortable for you, but we're all kind of all talking about the same thing.

We do recognize that there's a range of views on this issue, and that's really why we're here today. We want to hear from you and hear your views and your perspectives on this issue. So, these public meetings are an opportunity for the public to provide

comment on this education and outreach initiative, and we're interested in your comments on three key questions, and those are listed there on the slide. So, these are the questions that we posted in the Federal Register notice that was released as part of this public meeting. They're specifically geared towards helping us as we develop this education and outreach initiative.

The first question is: "What are the specific topics, questions or other information that consumers would find most useful regarding agricultural biotechnology, and why?"

The second question is, "Currently, how and from where do most consumers receive information on this subject?"

Then third, "How can the FDA, in coordination with USDA, best reach consumers with science-based educational information on this topic?"

So, today's meeting is an opportunity for the three agencies to hear from you all your thoughts on these questions. Your input will help us as we develop and implement this education and outreach

initiative.

I have a list here, it's also in your folders, of the folks that have registered ahead of time to provide comments. We will likely have some additional time on the agenda, so if you are here and you didn't register but you feel like you do want to make a public comment, please check in with Juanita Yates. Juanita, could you stand up just for a second? That's Juanita, bright blue jacket, so you'll be able to find her. So, just let her know during the break or any time during the day if you do want to provide a public comment, and she'll make sure you get added to the list.

We are asking each commenter to limit their comments to about ten minutes. That way we make sure everybody has an opportunity to provide comments. If you do start to go over that ten minutes, I'll you to kind of wrap it up so we can move on to the next person. And then we do have some folks here at the table here with me who I may turn to and ask if they have any clarifying questions. So, don't run away from the mics, just stay for a second. I'll check to see if

they have any clarifying questions, and then we'll move on to the next person.

So, in addition to public comments, if you want to do written comments, you can do those as well. You can submit those either electronically or through written paper submissions. The information is up here on the slide. The due date for those comments is November 17th, 2017, so you'll need to get those in pretty quickly. That same information is also in the Federal Register notice in your packets, so you don't have to write this down. It's all in there and you can access it that way.

Finally, we are transcribing and webcasting today's public meeting, so a transcript and a webcast will be posted on FDA's Meeting Agenda in the coming weeks as soon as we get it available, so you can look for that on our website.

Your comments today are very important. They're going to help us as we develop this initiative, and it will help inform both the development and the implementation of this initiative. You're going to help us determine the specific topics

that we cover in the education materials that we develop, the format of the materials, and the methods to disseminate that information to the public. We are conducting some other activities to gather public information in addition to these two public meetings. So, we are doing a scan of all the consumer research that is currently available on public perceptions and public attitudes regarding agricultural biotechnology. And we'll also be doing focus groups with consumers as we begin to develop materials and concepts. We'll be doing those focus groups to get their perspectives on those once we start developing those materials.

In terms of timeline, we hope to begin to roll out this education and outreach initiative in the next 18 to 24 months. So that's about the time frame you can start looking for some of this stuff to start rolling out.

Before we get started, I do want to introduce the folks that are here on the table with me so you know who's here. These folks represent some of the other agencies that are involved in this project with us.

First is Jason Dietz. Jason is the policy analyst in the Office of Food Additive Safety at the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration or the FDA.

Next to Jason is Ed Jhee. Ed is the Director of Regulatory Operations at the Animal and Plant Health Inspection Service at the U.S. Department of Agriculture.

Next to Ed is Mark Perry. Mark is Senior Advisor in the Emerging Technologies Branch in the Office of Pesticide Programs at the Environmental Protection Agency or the EPA.

Now I would like to turn the podium over to Jason, the policy analyst at FDA, to give some very brief remarks on the government's role in agricultural biotechnology. Jason.

FEDERAL GOVERNMENT'S ROLE IN REGULATION OF AGRICULTURAL BIOTECHNOLGY

MR. DIETZ: Thank you, Chris. My job this morning is just to give you a high-level overview of the federal government's role in the regulation of agricultural biotechnology products. With my

presentation, I'm hopeful that you will get a flavor for how the agencies up here today coordinate with each other to make sure that these products are safe and lawful.

Biotechnology can be applied to agriculture in a very broad sense, and a breadth of products can be produced using this technology. In fact, some of these products may have characteristics that fall within the regulatory jurisdictions of more than one regulatory agency. In fact, biotechnology products are regulated in a coordinated fashion by multiple agencies using the applicable laws. So, for instance, it's possible a product may be regulated by one agency or multiple agencies, depending upon the characteristics of the product.

This coordinated approach was laid out in 1986 in the Coordinated Framework for the Regulation of Biotechnology Products. It was updated in 1999, and more recently was updated in 2017. If you're interested in more information about the Coordinated Framework, the 2017 update contains a very detailed chart explaining the types of products that might be

regulated, the agencies that regulate those products, and the focus of each agency's regulation. For example, are they focused on food safety or environmental safety?

Agencies often involved in the regulation of these products may include the Food and Drug Administration, the Environmental Protection Agency or EPA, and USDA's Animal and Plant Health Inspection Service, or APHIS. We're very pleased today to be joined by colleagues from EPA and APHIS.

For example, a genetically engineered plant, depending on its characteristics, could be regulated by FDA for food safety purposes, it could be regulated by EPA for pesticidal purposes, and it could also be regulated by APHIS for any plant pest purposes.

A way to think about this coordination is that it applies the government's experts in food safety and food safety aspects of the product, the government's experts in pesticides to the pesticidal aspects, and the government's experts in plant pests to the plant pest issues associated with a product.

The role of the regulatory agencies of

course is to ensure that these products are safe and lawful. They do that by performing food safety evaluations, environmental safety evaluations, and looking at plant and animal health issues.

While there is a broad range of agricultural biotechnology products and multiple agencies involved, there are some guiding principles for regulations. One of those is that agencies use their laws and regulations to ensure that products are safe for their intended use. Also, collectively agencies work to make sure that their programs capture the full spectrum of organisms that may be produced through biotechnology. This could include animals, plants, microorganisms, and any other organisms.

Finally, and very importantly, agencies perform science-based safety assessments taking into account the product, the product's characteristics, their intended uses, as well as the environment into which they will be introduced to ensure that these products are safe and lawful.

This is a very high-level overview. If you are interested in more information about the agencies

or any of their programs, I would strongly encourage you to visit the agencies' websites. They all have a wealth of information about the laws underpinning the regulation, the way each agency implements that law, and also information about the products that have been evaluated by each agency.

So now I'd like to shift gears and talk a little bit about today, and I'll repeat some of what Chris has mentioned. We recognize that there's a wide range of views on agricultural biotechnology. This is an opportunity for you to share your views with us, particularly in response to the questions that we issued in the Federal Register.

Your input is very important to us because it will help us develop and implement an outreach and education initiative. So, we are very appreciative of your time today and your thoughts, and we very much look forward to hearing your comments. Thank you.

MR. WALDROP: Thanks, Jason. I appreciate that. Hopefully that gave you all just a little bit of context in terms of the background of the agencies, but as Jason mentioned we are really here to get your

comments on this education and outreach initiative that we're embarking on.

STAKEHOLDER INPUT AND COMMENTS

MR. WALDROP: We're going to begin the public comment portion of the agenda now. I will go down the list of commenters and call you up by name one by one, ask you to step up to the microphones here at the front. Please introduce yourself and if you're with an organization, that organization, because that will give us a good sense as they transcribe the meeting. Again, please keep your comments limited to ten minutes so that everybody has an opportunity to provide their comments. If you do go over the allotted time, I will ask you to wrap up your comments so we can move to the next person. And then at the end of your comments, I'll ask the folks here at the table if they have any clarifying or follow-up questions.

For those of you on the webcast, we will have a separate portion towards the end of the meeting where if you have any questions, we'll provide you an opportunity to put those questions in. So, if you're thinking of any now, just kind of jot them down and

then I'll let you know when we get to that point.

So, moving to the very first commenter, and I apologize in advance if I mispronounce any names, please correct me. Elizabeth Beisel.

MS. BEISEL: Good morning. My name is Beth Beisel. I'm from Farmington, Connecticut. I'm an unpaid volunteer who helped Connecticut become the first state in the country to pass a GMO labelling law. That law was passed in June of 2013 by a vote of 134 to 3 in the House and unanimously in the Senate. Subsequently it was preempted by the federal government, and Connecticut lost its right to require simply worded on-package GMO labelling.

I'm here to ask you to reconsider spending three million taxpayer dollars to promote GMOs. But I also want you to think about your own families, your children and grandchildren and future generations. Most of us know someone with food allergies, autism, ADD, ADHD, digestive problems or autoimmunity. In my testimony today, I will talk about my own experience as a health professional. My written testimony will include links to studies connecting these chronic

illnesses to GMOs.

My background is in nutrition. I'm a registered dietitian in private practice, but I'm also a mother and I care deeply about providing the healthiest food possible to my family and making healthy food available for all Americans, not just the ones who can afford to buy organic. I'd like to tell you about some of my experiences with my clients who got better once they removed GMOs from their diets. One was a 20-year-old female with chronic stomach pain and dysmotility, who improved within two weeks of cutting GMOs out. Another middle-aged female had long-term constipation and chronic fatigue. She was already on a GMO-free diet, but we discovered that a vitamin she was taking contained a GMO corn derivative, calcium citrate. Once she switched it out for a non-GMO equivalent she got better. By the way, over 90% of the corn in the United States is genetically engineered. Another was diagnosed with Hashimoto's autoimmune hypothyroidism, but after she removed all corn products from her gluten and dairy-free diet, her test results came back negative for antibodies to

Hashimoto's, and her doctor was dumbfounded.

In addition to working with private patients, I consult with a subacute care facility, I work with young and elderly adults in group homes, many of whom cannot speak for or grocery shop for themselves. And I work with severely autistic children in a residential school. In the last 15 years, shortly after GMOs were let into our food supply without our knowledge and without our consent, chronic diseases in children have been growing at an unprecedented rate. Diseases like celiac, diabetes and autism are touching the lives of almost every community in America. Ten years ago, a CDC report estimated that severe food allergies affect three million children. While correlation does not equal causation, it can't be overlooked.

Think about this for a second: When we were in school, how many children had to sit at allergen-free tables? How many children were on inhalers? How many children were autistic or had explosive disorders? How many children needed personal aids to monitor and assist them in school? When did you first

hear the term autoimmune disease? Now every school nurse's office has multiple inhalers, EpiPens, and psychiatric evaluation reports for children on psychotropic drugs like Ritalin and Adderall.

This isn't happenstance. Something is going on. What has caused this epidemic of chronic disease in children? Could it be related to the fact that at least 40% of the population has some genetic mutation like MTHFR that inhibits their ability to detoxify? Has the introduction of GMOs and the pesticides they were created to withstand added to the toxic burden that these vulnerable children are faced with, resulting in a toxic load that is eventually too much to bear, so that suddenly, once that toxic threshold is reached, they are diagnosed with a chronic illness?

Autism has grown at an alarming rate from one in 10,000 a few decades ago to one in 68 today, and it's not just because we've gotten better at diagnosing. There is a vast body of medical literature indicating that the increased rates of everything from autism to asthma are due to true increases in disease, not just better diagnosis or better patient capture.

It is a real epidemic, and the rates of these disorders are increasing so quickly that the causes can't possibly be from genes alone.

What about the economic costs of this exponential growth in childhood chronic disease? Should the short-term economic gains from selling cheap, fake food trump our health and future economic stability? Again, my written testimony provides studies that show a potential correlation between GMOs and the diseases I'm talking about.

But I also want to stress the financial impact of these diseases on our economy. Autism costs the United States $268 billion a year with a potential to reach one trillion by 2025. What we pay to manage autism in this country on an annual basis is more money than has been spent on the entire NASA program since 1971. Asthma, affecting one in eight children, one in six African American children, costs the United States $56 billion per year. One in five children entering kindergarten carries a mental health diagnosis. The U.S. spends $83 billion a year on pediatric depression.

So as the number of vulnerable children suffering from chronic illness multiplies, billions upon billions of dollars spent annually to care for them may break our nation. I see this first-hand in my residential school for autistic children. Many need 24-hour one-on-one supervision. This generation of children growing up in the United States is a threat to our economic and social stability. My whole point today is to ask you to consider that GMOs might be a part of the problem. They might be contributing to the toxic load I mentioned. So, it would be prudent to use the precautionary principle before allowing more of these questionable foods into our food supply. It is not prudent to promote them as safe and beneficial. There are no comprehensive long-term independent studies that prove that these patented unique genetically manipulated foods which contain novel foreign proteins are safe for long-term human consumption.

The FDA has not done its own studies to prove that GMOs are safe. They rely on industry to do the studies to prove they're safe. The FDA says GMOs

are substantially equivalent. Then why are they patented when a patent is supposed to be a claim on something that's unique and novel?

Years ago, the FDA's Safety Policy included these words: ultimately it is the food producer who is responsible for assuring safety. Yet, here's a quote from Monsanto's Director of Communications in 1988: "Monsanto should not have to vouchsafe for the safety of biotech food. Our interest is in selling as much of it as possible. Assuring its safety is the FDA's job." The American Medical Association's policy states that GMOs should have pre-market testing before they hit the market. The Academy of Nutrition and Dietetics position statement in part said more research is needed to determine the impact on human and environmental health. We should let science prove safety through long-term independent peer-reviewed studies before we go promoting them with taxpayer money. Why not use the $3 million to do independent safety testing? Industry has spent well over $100 million to prevent GMO labelling and promote GMOs. They fund expensive political campaigns, first-rate

public relations efforts, slick websites and aggressive litigation. They fund front groups and operatives, hire well-connected lobbyists, and organize trade groups and social media campaigns. They attack scientific and journalistic critics.

I'd like to end my testimony by reading a quote by Dr. Martha Hebert, a pediatric neurologist with a Ph.D. as well from Harvard Medical School. "We cannot maintain the illusion that one lives in a comfortable and rational world where new chemicals and technologies always mean progress, where experts are always objective and thorough, where corporations are honest, and where authorities can be trusted. That human actions rather than genetics might be responsible for compromising the health of a significant portion of a whole generation is unthinkable."

MR. WALDROP: Thank you, Beth. Any questions? Clarifying questions from the panel?

Next on the list is Bryant Chapman. We do have microphones up here, so you can use those as well.

MR. CHAPMAN: Good morning. As formerly

mentioned, I'm Bryant Chapman. I'm representing Chapman Jersey Farm, which is in Taylorsville, North Carolina, and I'm also here on behalf of the Dairy Cooperative, DFA, which stands for Dairy Farmers of America. Currently my family and myself, we own and operate Chapman Jersey Farm where we milk around 210 cattle, also running beef cattle for beef production, managing poultry houses, and growing a multiple variety of crops.

As a dairy farmer, I appreciate the efforts by FDA to educate and better inform consumers about the benefits and safety of agricultural biotechnology, which as we've stated is also known as GMOs.

As stated in the 2016 disclosure legislation, milk is non-GMO regardless of the feed the animal consumes, but nevertheless the technology is important to us as dairy farmers and to global agriculture as a whole because it improves our ability to meet the food needs of the future in ways that conserve our natural resources and protect our environment as well.

The majority of the feed the animals consume

today comes from some type of plant that has received a beneficial trait, whatever that may be, through biotechnology. I believe it's important that we educate consumers so that they know how this technology has helped me and my fellow farmers over the past several years.

A few notes on what we've seen as far as changes from biotechnology, positive changes I may add, in the last couple of years. For example, in the last 20 years we've been able to use less and safer crop protection chemicals because of the biotechnology with the crop yields that we're using.

The environmental footprint of farming has also been significantly improved, whether we're talking about the lower greenhouse gases emitted, lower fuel use because of fewer trips across the field, and because of improved soil health which goes back to the fewer trips across the field, less tillage, less traffic, a lot less use of our land and preserving it as well.

We now have greater assurance as well that our yields that are always subject to forces of nature

year in and year out. Personally, our farm seen a force of nature two weeks ago in the way of a tornado that set us back significantly, but that's things that we deal with and we move forward. But because of biotechnology in these crops, we've been able to see a sustaining yield year in and year out. Because of biotechnology that's been put in the corn that we use now, a lot of our corn that we will use later on in the winter here, the shell is still standing and doing strong even though we had significant winds. So, for us that's an improvement that allows us to provide for each and every one of you sitting here today as well as the other consumers.

These benefits are very consistent with things that consumers tell us are important to them, which is high quality food that is affordable and grown in ways that conserve our natural resources and chemical use. But it's very clear that most consumers aren't making the connection between what and how GMOs help to accomplish that. It's up to all of us first to listen to them, and then second, share our personal stories to help them understand.

If we don't do a better job at communicating this, then the implications go far beyond our ability to use the important technologies available here to us in the United States.

Experts tell us that there are huge opportunities for GMOs to help reduce food insecurity, hunger, and economic growth in other parts of the world, especially in developing areas where safe options aren't currently there to protect crops against diseases and pest whenever these people are very limited in their production.

We can make an impact by helping those others by proving that technology helps here in the United States where we have the ability to use it and practice it safely. But if we don't engage with the consumers here in the United States, then we can see a potentially life-threatening ripple effect by losing these technologies and not being able to use them in developing countries.

Although milk is not bioengineered and is exempted from labelling or disclosure, dairy farmers are still concerned about the widespread food

marketing against GMO technology. Many food companies are labelling and promoting products as non-GMO or organic or things of the like, and are trying to reinforce confused consumers that GMOs or biotechnology as a whole are things that they need to avoid, and that's just not the truth.

As a dairy farmer, I welcome efforts led by the FDA that will lead to better informed consumers with a greater awareness in the implications of food choices and a stronger foundation as they make food decisions.

As I just stated, I realize milk is not labelled or not considered as a GMO product, but as an example using milk that can apply to other food items as well, you go look at a gallon of milk in a store now and I'll almost guarantee you you're going to see no antibiotics ever used or something to that extent. That's a good marketing gimmick, but I'm here today to tell you that milk cannot leave my farm or any other dairy producer's farm if antibiotics are found. So, while that's a great thing and I wholeheartedly agree that's the way it should be, that labelling that's put

on that gallon of milk is just a marketing gimmick, when in truth we know that no milk ever reaches a store shelf or ever gets to a consumer's hands without being antibiotic-free. And I use milk as an example because I know other food items are doing the same thing through this deceptive marketing.

I feel that it's important that we inform the consumers about this deceptive marketing and labelling and that we take action to inform them and educate them about it so that they'd realize what they are truly getting whenever they go to the store to purchase their food items. These practices are currently hurting farmers like myself and a lot of my neighbors and fellow farmers who are trying to do an excellent job every day to take the products that they are producing and produce them safely, and this marketing is then taking them and making them appear as unsafe or harmful when in all reality our goal day in and day out is to make sure we produce the safest thing available for anybody to consume. That's our number one goal, to do that and to take care of our livestock in the best way possible.

An idea that we think would be appropriate this issue and was mentioned in the previous testimony is social media. We see a lot of people opposed to GMOs or agricultural biotechnology using this platform as a way to attack those who are conventionally producing these items. There's already many individual farmers who are doing a great job of trying to educate through these platforms, but I think it would be nice to see some bigger organizations such as the USDA or the FDA get behind, not sponsored ads, I'm saying to promote but to educate instead and put the true facts out there instead of deceptive things like previously mentioned.

I see often ads from the opposition that I know without a doubt because of my experience producing milk, beef, poultry and food crops, that are using these deceptive strategies that I know with [sic] a shadow of a doubt are not true because I'm involved in many various sectors and know that that can't happen for us to be able to produce that product.

I would be more than glad to help personally

as well as Dairy Farmers of America would to help in educating and producing more true facts for the general public and suppressing the false ideals that some are using to manipulate against American farm families through whatever platform they are using to reach the individual consumers.

I'm not a communications or consumers research expert, but as a farmer I know the importance of telling the story of my farm to my neighbors and my community as well as to all of you. I hope FDA will be able to work with real people with real stories who can help reach consumers with accurate, trustworthy information that is also grounded in science. Thank you.

MR. WALDROP: All right. Any questions or clarifying questions for Bryant?

MR. DIETZ: Thank you for your comments. One of the things I think I heard throughout your comment is that oftentimes consumers may not understand how these products are helpful to farmers. Is that correct?

MR. CHAPMAN: Yes, sir, absolutely.

MR. WALDROP: Thank you. Next is Kate Creasey.

DR. CREASEY: Good morning. My name is Dr. Kate Creasey and I am the president of Grow More Foundation. The Grow More Foundation is a 501(c)(3) nonprofit organization based in New York. Our mission is to promote transparency and awareness of biotechnologies in agriculture. Our team is made up of established internationally recognized scientists. We believe in order to ensure global food supply and security and safety we need to work together with industry and regulatory bodies to establish an open dialogue with the public on this issue.

We are here today to address the questions put forward in the Agricultural Biotechnology Education and Outreach Initiative. Through our own studies and others, we identified three specific topics that consumers would find the most useful. Safety, general concerns of this topic for the environment and human or animal consumption. Awareness, a general lack of understanding of the food industry and farming. Finally, transparency, a

perceived conflict of interest with industry and a lack of factual information.

The safety of GMOs is a polarizing and dividing issue with the majority of scientists considering them safe, and yet the complete opposite in society. There is a clear correlation with information or at least the access to it and level of understanding with acceptance. However, one simply stating that biotechnologies in agriculture are safe is simply not enough. Are genetically engineered and/or genome-edited foods safe for the environment, safe to eat? To alleviate concern, public safety consistence, we should provide a third party independent peer review of the safety data. We should explain the entire process from lab to farm to field to table. The insect and animal studies, toxicity, and allergenicity testing. Did you know that genetic engineered foods are the only foods to actually go through an entire allergenicity testing poll? So, if you do have a peanut allergy, you can be safely assured that genetically engineered or GMO foods don't contain the peanuts. They're not going to give you the

allergy.

Detachment from the issues facing food production as well as being too far removed from the struggles, the daily struggles facing farmers today as we just heard, also adds to this sort of negative perception and distrust of industry who are trying to actually help the farmer meet the demands of the consumer.

In particular there's also the hidden and undisclosed information associated being in the corporate world. It is complicated. It's complicated to search for data, to go through long reports, the actual wording of them, so easy to misinterpret both mechanistic information. Not only does this promote confusion, but it also leads obfuscation of the facts. Many unregulated, unqualified opinions are out there for everyone to see. They dominate the dialogue, simply due to a lack of familiarity, maybe a lack of a Ph.D., or simply the pseudoscience is more easily understood.

Are people sufficiently aware of the processes of food production, farming and the

agricultural industry? I'm an academic with a background in plant genetics of about 15 years. Ph.D. from Edinburgh University, post-doctoral fellowship at Cold Spring Harbor Laboratory, world renowned institutions, and yet I find it difficult to find all of this information easily laid out to be understood. Academia, industry, and regulatory bodies must work together in order to work for the public to provide open access for all the information.

We identified that consumers do not know where to look for clear, transparent, reliable, non-conflict information. However, they do trust scientists and academics. Yet there is a perceived conflict of interest with a majority of the groups providing this information due to being directly funded by industry. This is exactly why we're here today. We're discussing how to come this through the education outreach program.

Is there a need for a neutral, third-party, non-conflict source to provide information to debunk myths, pseudoscience and provide clear information all access? Providing easily digestible and accessible

information, peer reviewed by academics and aimed at the public shall hopefully allow society to make their own minds up, at least to debunk the pseudoscience for themselves.

From our surveys, two principal sources where consumers receive information are the internet, search engines, social media, and specific groups targeting both for and against. And academia, schools, universities, doctors, professors. However, we also found that the internet was the least trusted source. Obviously, this could be due to a wide range of reasons including anonymity, bot-netting, lack of verification, lack of references, peer review, or a direct conflict of interest.

At least academics are considered trusted sources; however, relatively few have direct access to them. Interested individuals should be able to self-educate. They should be able to find the information derived from a neutral, qualified, non-conflict, non-industry-funded, independent source. We hope we can help with that.

Finally, the FDA and USDA we believe should

collaborate with non-conflict, non-industry-funded, nonprofit organizations that provide services that complement ongoing efforts, in particular education and communicational safety. Advise and ensure curricula are designed to cover modern agriculture so that we can become more aware of what actually happens with our food industry and farming from a young age. And of course, provide independent review of all the biotechnology that we have, and currently as well as in the future promoting the technology and the safety aspects for all who wish to understand, learn and become to accept this great technology that could help with the problems we're facing in the world today.

Thank you for your time and your attention. Any questions?

MR. PERRY: I think the third-party assessment idea is interesting. Could you break that up a little bit as far as how think that would work or what groups would be involved?

DR. CREASEY: Of course. So, by third-party assessment, we're basically saying that the data that industry normally is creating, is finding, they just

come up with an idea and it goes straight to the FDA for approval. There's a long process, up to ten years of lab work, field trials. There's a lot of information there. Now bits of it obviously go all over the world, depending on where it's regulated. The three regulatory bodies who are here today, the EPA, USDA, FDA, look for particular parts that they deem necessary for acceptance of whether or not they pass. However, unlike a drug which once goes FDA approval, everyone accepts the drug and people start taking it, regardless of if they have their issue and the side effects, foods don't seem to pass society's approval as well once FDA approves. So, we're wondering if we can provide the third-party assessment to actually look at all that data with qualified academics, both with specialties and field trials, animal and insect studies, general mechanistic action. So, we're talking the whole picture. And we can do that. That's what we're specialized in and we have the time to do. And we can provide those findings in an easily understandable format for the lay audience to see the raw data so they can get their hands on everything,

and hopefully give you a chance to understand it for yourselves. But we would that collaborate with everyone who wants to with us. Hopefully that answers your question.

MR. WALDROP: Thank you. Any other questions? Thank you.

DR. CREASEY: Thank you. Oh -

[Inaudible question]

DR. CREASEY: Would you like to use the microphone?

MS. RICHARDSON: On the third party or how to bring all the data together, I was on the pharma side previously and as you know ClinicalTrials.gov does a lot of that. So, it takes a lot of the trial data, all the pharma companies are required to put their data on there. I mean, some of them are a little bit delinquent, but realistically that's what they're supposed to do. That might be one way to get the data out into a neutral place that consumers can review it, similar kind of setup.

DR. CREASEY: Like clinical trials for human drugs, we have the similar aspect for food. Exactly.

MR. WALDROP: Thanks, Kate.

DR. CREASEY: Thank you.

MR. WALDROP: And we will set aside some time towards the end for a broader discussion, so we can have that sort of interactions, but for now let's try to keep it to the public comments so everyone can get their comments out. So, the next person is Diana Reeves. And again, we have microphones here at the front if you'd like to use those.

MS. REEVES: Good morning. I'm here today as the strictly unpaid Executive Director of GMO Free USA, a public interest, nonprofit and pro-science organization. We fully support responsible science and advocate for the precautionary principle. I'm here as a concerned parent and as one of four members of a family with digestive and other chronic health problems.

Through cancer lawsuits brought by people who have developed Non-Hodgkin's lymphoma after exposure to Monsanto's Roundup herbicides, the world has gotten an up-close-and-personal look at the corrupt and unethical culture of the Monsanto Company.

The recent release of explosive internal emails and documents dubbed The Monsanto Papers has proven that biotech giant Monsanto has displayed a long list of corrupt and unethical behaviors. The company has used inadequate and manipulated scientific studies to prove the safety of its products, has ghostwritten studies and articles for scientists who were presented as independent, used front groups portrayed as independent, bullied scientists, employed an army of internet trolls to leave no comments unanswered, and has covered up concerns of carcinogenicity and genotoxicity of its glyphosate-based herbicides, all in the interests of gaining regulatory approval for unsafe products.

Even Monsanto toxicologist Donna Farmer was caught in an email saying you cannot say that Roundup is not a carcinogen. We have not done the necessary testing on the formulation to make that statement, nor has the company done the necessary testing on any of its genetically engineered foods to be able to prove they are safe for long term human consumption. The company has recently been banned from entering the

European Parliament after refusing to attend a hearing into allegations of regulatory interference.

This is a company that puts corporate wealth before public health. This is not a company that we can trust to do adequate and unbiased safety studies of novel foods created in their laboratories. It's time for U.S. regulators to stop turning a blind eye. Let's look at some documented examples of this corruption as it relates to the genetically engineered foods currently approved and in our food supply.

This is an industry that rushes their products to market with only 90-day animal feeding studies, that are classified as trade secrets to protect them from the scrutiny of independent scientists. In 2006 a lawsuit by an NGO resulted in the forced release of a Monsanto 90-day GMO rat feeding study by an appeal court in Germany. A new analysis of the data from this study was published in the peer reviewed journal Archives of Environmental Contamination and Toxicology in 2007. The study documented signs of liver and kidney damage causing the researchers to conclude with the present data it

cannot be concluded that GM corn Mon 863 is a safe product.

Let's look at the review article titled Prevalence and Impacts of Genetically Engineered Feedstuffs on Livestock Populations by former Monsanto employee Alison Van Eenennaam, published in 2014 in a journal with a Monsanto employee on the Scientific Advisory Committee on Biotechnology. This review has been widely touted by industry as proof of safety after 100 billion animals were fed GMO feed with no harmful effects. A closer look disturbingly finds that nearly 95% of the animals under review were broiler chickens, which would live for at least five years but were only fed GMOs during their limited commercial lifetimes on average for the 47 days up until slaughter. Seriously, how many chickens are there in the audience?

This review is based on animal production data which looks at days to market, feed efficiency, percent mortality, and carcass weight, and does not study health parameters. You have to be absolutely insane to think that this pseudoscience is proof of

safety.

The basis of the FDA's GMO approvals is the concept of substantial equivalence, meaning that the GMO is presumed to be compositionally the same as the non-GMO counterpart. A recent study published in the journal Nature, used multi-omics to analyze Monsanto's NK603 Roundup Ready GMO corn and compare it to its non-GMO counterpart grown side by side under identical conditions. A total of 117 proteins and 91 small molecular biochemicals were found to be significantly altered in the Monsanto corn, unintended effects of the GM transformation process.

The lead author was quoted saying that the GM transformation resulted in worrying large increases of putrescine and cadaverine, which can produce various toxic effects. The authors concluded our molecular profiling results show that NK603 and its isogenic control are not substantially equivalent. In the EU, the London Times published an article titled Millions Face Health Risk from Toxic GM Crop.

The problems here are not limited to Monsanto. Most if not all pre- and post-market safety

studies conducted by biotech companies and sent to regulators use laboratory animal diets fed to the control groups that also contain GMO ingredients. In a study published in the peer-reviewed journal PLOS ONE, conducted by independent researchers, they observed that the standard laboratory control diet almost always contained significant amounts of Roundup Ready soy and corn and BT corn. Thus, in these safety studies both the control group and the test group are fed GMO ingredients, which makes both the results of those studies and the historical data used to represent so-called baseline incidence of disease unreliable.

Our nonprofit organization examined the health studies from 1993 to 2014 as listed in an article published in the journal Nature Biotechnology, written by Miguel Santos who is funded by the biotech industry. What we found were numerous omissions. When we include all peer reviewed studies during that period, adding in those omitted, 76.2% of the animal health studies using rodents and pigs fed Roundup Ready soy observed potential and actual adverse health

effects. That's more than three-quarters of the studies on the most used genetically engineered crop in the US.

These are studies using pigs and rodents, which are some of the most comparable animals to humans, not chickens. The damage reported in these studies includes but is not limited to disturbance in the pancreas, liver, kidneys, adrenal glands, thymus, ovaries and testes, reproductive issues such as lower birth weight and increased mortality of offspring, and the functioning of the digestive system.

One study published in the journal Animal Breeding and Genetics, which resulted in stillborn piglets in the GM soy fed group caused the researchers to conclude the use of GM crops in food for children, adolescents and young people should be prohibited.

In fact, several countries have banned the use of GMOs in infant formulas and baby foods. When we examine the studies which did not claim to observe adverse effects, we found that they were all fundamentally flawed. In nearly all of these studies only a limited number of health parameters were

examined. For example, one study only looked at the aortic valve of rats. This tells us nothing about what's going on in the liver, kidneys, etc. It's equivalent to a physician giving you a clean bill of health after doing only an MRI of your big toe.

In 2016 the National Academy of Sciences published a report on GMOs. Aside from evidence that members of the committee that wrote the paper had undeclared conflicts of interest, we determined that the NAS report had the same flaw of omitting dozens of studies. Groups such as the NAS, however, represent a minority. On our website we list over 300 independent medical, public health, and science groups that question the safety of GMOs. These groups represent the overwhelming majority of such groups from around the world. The surveys of physicians and other members of the public health community also consistently show that health professionals either regard GMO foods currently on the market as unsafe or state there is not enough evidence to claim safety.

In 1957 researchers, including Dr. Fred Kummerow, presented evidence of harm from artificial

trans fat in the Journal of Science. Dr. Kummerow continued his research on *trans* fats into the 1970s. Yet in 1976, the FDA considered *trans* fats generally recognized as safe for human consumption. It was not until 2015, almost 40 years later, that the FDA determined artificial *trans* fat is not generally recognized as safe. At that time, FDA's acting commissioner Stephen Ostroff, M.D., said, this action is expected to reduce coronary heart disease and prevent thousands of fatal heart attacks every year.

Please don't make another mistake like those made with artificial *trans* fat. The science of genetics is in its infancy. There is far more to be learned than is currently understood. Genetic engineering technologies are based on the outdated notion of one gene per protein. There is now ample evidence that the GMOs currently on the market are unsafe. This three million of taxpayer dollars should be spent to evaluate independent safety studies and do further research so thousands of lives aren't lost like they were with artificial *trans* fat. It's outrageous that the FDA plans to spend any money at

all to promote an industry that spent over $100 million, 46 million plus in the State of California alone, to fight state level GMO labelling. It is not the role of the FDA to promote industry. The FDA is responsible for promoting and protecting public health by assuring the safety, efficacy and security of our nation's food supply. Please do your job. Thank you.

MR. WALDROP: Thank you, Diana. Any questions from the panel?

Next we have Don Duvall.

MR. DUVALL: First of all, thank you for the opportunity to address you. Again, my name is Don Duvall and I am a grain farmer from southern Illinois, so I'm speaking to you on behalf of grain farmers. I am also a member of the National Corn Growers Association, so I'm here representing them as well.

It is my pleasure to represent grain farmers, many of whom would also be here to make comment, but right now it's in the middle of harvest, so it's kind of a bad time to have a presence here. Thankfully my harvest is done on my farm, so I can make this opportunity.

I guess a lot of my comments will kind of mirror what Bryant has said. I'd like to point out that as a farmer, and every farmer that I know, there is kind of a common goal or common objective to produce the best product they can. And biotechnology helps us do that. Not only the best product but one that is produced in an environmentally and sustainable way. And we're producing more safe food and feed products with fewer inputs, and that's thanks to biotechnology.

We use less fuel, less chemicals, less insecticides, less herbicides, less water, less tillage, and consequently our environmental impact has shrunk while we are – our production has increased. So, everyone kind of wins with a more affordable food and a healthier environment.

In addressing the three questions that you all posed as to what topics do you think are important to recognize, I think as Jason pointed out earlier, one important thing is to reassure the consumer that their food is safe, that GM are some of the most extensively tested products that are out there. As has

been mentioned, they are actually tested by sometimes multiple agencies, the FDA, the EPA, the USDA, and sometimes more than one.

Also in the safety aspect of that, that is in the more than two decades that GM products have been grown, there has not been a single documented instance of harm to human health resulting from genetic modification. I think one of the earlier speakers called that recognition does not equal causation, and I thought that was a good point to make. And in fact, there has never been a documented case attributing it just to the GM aspect of it. So, I think that's one important topic that should be put out to the public.

A second one is that the GMOs reduce the impact of agriculture on the environment. As both Bryant and I have said, we're using less fuel, less chemicals, less inputs, and that results in a healthier environment.

In question two, in regard to where are the consumers receiving most of their information, sometimes I think some of it is misinformation, and I,

too, think that's the internet. More specifically, social media, things like Facebook. And while I think that is the right place to be addressing the issues, through your agency and others that have been mentioned, I think I would add to what Kate said, that there should be a place where you can have an extensive, science-backed explanation for the people that are interested in receiving that type of information. But I think from a greater standpoint, it needs to be presented in a format that is short and concise and easy for consumers to understand. Because quite frankly, most people don't have the time or the inclination to do extensive research to satisfy their notion but would accept short, concise sound bites if you will.

And then the final, how can the FDA – I guess I would just like to thank you, the FDA, for the work that you have done in the past in messaging, and also encourage you to serve as the lead agency in continued messaging to consumers regarding biotechnology. So, any questions?

MR. WALDROP: Any questions from the –

MR. DIETZ: You had mentioned the possibility of an internet platform that could be used for stakeholders to go and obtain information. If you have examples of such platforms, we would certainly be interested in hearing it and recognizing that you may not have one at the top of your mind now. Please feel free to submit that to the docket. That could be useful.

MR. DUVALL: Okay. I think one that probably would serve, the one that National Corn Growers has been involved with now for more than seven years is the U.S. Farmers and Ranchers Alliance and Common Ground are two platforms that address these issues.

MR. WALDROP: Any other questions? Next, we have Margaret Richardson.

MS. RICHARDSON: Thank you for your time. I appreciate that. My name is Margaret Richardson and I am General Counsel for Anuvia Plant Nutrients Corporation. Anuvia strongly supports the need for education and outreach associated with agriculture and developing scientific trends to improve crop yields while reducing environmental impacts. Anuvia

represents a new way at looking at ag technology. We are using a unique patented process to remove organic materials from the waste streams. This does include products like bio solids, animal waste, and a variety of sustainable products from the food streams themselves. We create a sustainable fertilizer, fertilizer that has undergone extensive field trials and is proven to significantly improve crop yields, reduce volatilization of nitrogen, and improve soil health.

However, as a result of regulatory lack of understanding and general concern regarding food safety, we have struggled to receive approval in all 50 states. Most people do not realize that fertilizer is regulated on a state-by-state basis as opposed to nationally like pesticides.

Contrast that with a land application which is what happens to most bio solids directly out of wastewater treatment facilities. This product is then land-applied on a variety of different crops without any testing or approval by the state or federal regulatory agencies. It does not undergo any type of

QA or QC process, but is allowed to enter the food chain.

This lack of understanding as a whole in the industry results in fewer, lower crop yields and the inability to use the products in a way that would improve the overall crop and soil health.

Anuvia strongly advocates for education and outreach associated with new technology in the ag industry, and working together with parties to solve a variety of current and future issues such as improved crop yields, proper management of waste streams and soil health. In particular, we see that a lack of formal science and more importantly strong science education throughout K through 12 and into college is absolutely critical. Many times in the past you would often go to, as an example, to your local state fairs, and you would commonly see a lot of agriculture on display in a way that would allow the consumer to interact directly with the agriculture. At this point in time most of that has been removed, for again unfounded concerns associated with contracting *E. coli* or *Salmonella* for general contact with farm animals.

This has removed the consumer from understanding true agriculture, and as expressed by the Corn Growers and Dairy Farmers, this has provided a lack of transparency to those individuals. Again, for us, our key themes, if we're considering things to think about, are transparency related to scientific data that could be provided in a central location, general information that could be provided in a social media setting that would allow for an open exchange, and also oversight, and appropriate oversight by a variety of regulatory agencies. Although we never want too much, it is important to have agencies that are coordinated and working together to bring technology to the marketplace in a speedy and safe way.

In terms of other questions to think about, I do think as a group agriculture needs to spend more time in terms of educating the general consumers in many different formats. We work directly with the young farmers on social media to try to talk about products and technology, so again a forum or technology such as that I think would be the best way to begin this conversation.

MR. WALDROP: Thank you. Were there any questions from the panel?

MR. DIETZ: So if I understood what you were saying, one of the messages I heard there was that, and I think this resonates maybe with some of the other commenters, is that oftentimes the public may not understand all of the issues that go into producing food at the farm level. Is that correct?

MS. RICHARDSON: Yeah, I would definitely agree with that. As an example, when I was younger and I participated in the 4H, we had dairy cattle, and at the time we were required at the state fair to leave our cattle there for a period of time, like a weekend, to stay there. It was part of the process. And we actually had people would come up and say, well, can I get the chocolate milk because it comes out of the brown cows and white milk comes out of – so I think that lack of understanding of where food comes from is absolutely critical. We have to find a way to make that connection.

MR. WALDROP: Next we have Lisa Watson.

MS. WATSON: Good morning. My name is Lisa

Watson and I am Social Responsibility Officer of the Innovation Center for U.S. Dairy. Initiated in 2008 by dairy farmers through the dairy checkoff, the Innovation Center members collaborate pretty competitively on efforts that are important both to us and to our valued customers, things like food safety, nutrition, environmental impact, and animal care. I'm also a human nutritionist by training and mother of two, and the product of a family farm. So, thank you for the chance to come before you and talk a bit about your efforts related to educate and better inform consumers about the benefits and safety of ag biotech or GMOs. Most of what I say today will relate more on the question one that you offer, with a few on the other two.

As stated in the 2006 disclosure legislation, meat, milk and eggs are not genetically modified, regardless of the feed that an animal consumes, but nevertheless dairy farmers and other animal ag farmers in the whole value chain recognize the importance of technology both to U.S. and global agriculture. Tools like ag biotech are critical to our

ability to meet food needs of the future in ways that conserve our natural resources and protect our environment, and that's why I'm here today.

As we all know, a big chunk of animal feed comes from plants that have some beneficial trait or advantage that's conferred through biotechnology, and as a result the use of crop chemicals, especially insecticides, has significantly reduced over the last 20 years. A 2014 meta-analysis found that total pesticide use up to that time globally was down by about 37%, so it's a pretty significant reduction. In part because of better ability to implement conservation tillage practices and not disrupt the soil and conserve water, the overall environmental footprint of farming has really benefitted as a result of planting of a biotech seed.

As Mr. Chapman said earlier, another important benefit, when we talk about yield, it's not necessarily the average yield that we're talking about in terms of benefit, but we're talking about farmers being protected from these unexpected events like drought or a fluke insect pressure that comes in. So,

in the fact of these types of disruptions where in the past farmers may have lost a significant part of their yield, yield is largely maintained.

On the global scale, experts agree that technology like GMOs offer tools to significantly reduce food insecurity and hunger, and maybe even nutrient deficiencies depending on the trait that we're talking about. This is especially important in those parts of the developing world where they just don't have the same kinds of options that we have here in the United States to try and protect and provide an even yield.

These potential benefits have profound implications for global public health, and because as we know as of today there's not been a single documented adverse event or effect that's attributed to the products of biotechnology that are currently in the market. I think we have reason for confidence that the regulatory framework is doing a very good job in assessing safety of these products before they come on the market.

So, when we talk to consumers and ask them

what are the kinds of things that are important to you in food production, they say things like, well, they want high quality food, they want food that's affordable, they want food that is grown in ways that help conserve our natural resources, and where chemical use is minimized. It's kind of ironic, because those are very consistent with the kinds of benefits that we see from many of the applications of agricultural biotechnology today. But it's clear that these are very deeply held values for consumers, but they're also totally embedded in the values of our farmers.

But as we know, unfortunately there's a huge gap in the understanding between farmers and the benefits of ag biotech and the perception of the safety of these products, both from a health and environmental perspective. So, despite the very high interest in food and agriculture today, I would say, unlike any time I've ever experienced in my lifetime, still less than two percent of consumers have any direct connection with the farm. They're bombarded every day with information, and they're understandably

skeptical about what they hear.

Most of the public I would say has little if any recognition of how biotech has provided tangible benefits, of how biotech safety or GMO safety is assessed, and how to discern fact from fiction about these food and feed ingredients.

And although milk is exempted from disclosure requirements, dairy farmers, and I think you've heard this from several today including Mr. Chapman, are very concerned about the rampant food marketing against products of biotechnology. This kind of marketing has significant negative consequences. GMO absence labelling is further confusing consumers, clearly implying and reinforcing that GMOs are something to be avoided. We all need to do a better job of engaging the public and raising their IQ on how to interpret these free-from claims.

Consumers today are strongly influenced by their peer groups through social media channels as we discussed. Traditional forms of education and sharing of expert perspectives that I did earlier in my career are now no longer necessarily effective, especially

when we're talking about polarizing issues like the one we're discussing today. Unfortunately, the internet and social media have very few filters for accuracy and balance. I think we've got to find a way of connecting with shared values that consumers hold and that we hold, as the farming community and as government.

Our experience has been that when we have the opportunity to bring consumers into a farm, a dairy farm or other farms and we actually let them see how farming is done and the opportunity to ask questions and raise concerns or benefits or of various techniques with farmers, you just see an amazing transformation in those individuals. So, I think that while I recognize we can't bring the entire U.S. public onto a farm, I think that to the extent that we can engage with real people who are dealing with farming firsthand, that that would have a lot of benefit for consumers and help them understand the technology better.

Dairy farmers welcome efforts led by FDA and USDA that will lead to better-informed consumers with

a stronger foundation to make decisions about their food and greater awareness of the implications of food choices. Thank you.

MR. WALDROP: Any questions? Thank you. And finally, Todd Kuiken.

DR. KUIKEN: Good morning. My name is Dr. Todd Kuiken. I'm a senior research scholar at the Genetic Engineering and Society Center at North Carolina State University. The GES Center will be submitting more detailed comments into the official docket, but I wanted to take this opportunity to introduce the FDA to the GES Center and some of the work that we do.

The GES Center is a unique example of engaged scholarship that serves as a regional, national and international hub of interdisciplinary research analysis and inclusive dialogue surrounding opportunities and challenges associated with genetic engineering and society. It is unique in the nation and world in its blending of approaches from the natural sciences, social sciences, and humanities. The GES Center provides mechanisms for discussions and

rigorous, trustworthy analysis about how products of genetic engineering and synthetic biology may impact society and the environment.

I'd like to thank you for the opportunity to comment on the FDA's Agricultural Biotechnology Education and Outreach Initiative. We believe it is timely yet overdue for a robust public dialogue and engagement around these issues. Just yesterday the USDA withdrew its proposed rule to revise the agency's biotechnology regulations and will re-engage with stakeholders to determine the most effective science-based approach for regulating the products of modern biotechnology while protecting plant health. This reversal, along with the proliferation of TV and radio ads promoting GMO-free products that may or may not have ever had GM to begin with are examples of the complex and sometimes confusing set of rules, regulations, and advertisements that the public must digest.

While we appreciate the efforts that the FDA is undertaking, we believe these stakeholder dialogues and public engagement activities would be best

conducted by an independent trusted source like for instance the GES Center.

For instance, GES faculty Zack Brown and Jason Delborne are currently conducting an assessment on public perceptions of gene drives for invasive species and pest control funded by the USDA. The objective of the study is to analyze public perceptions and social values regarding important facets of gene drive technologies as they relate to agriculture and natural resources. Preliminary data from this study will be available this spring.

This is just one example of the work the GES Center conducts and we can serve as a resource for FDA and other agencies as they embark on their Education and Outreach Initiative.

On a completely different front, I work closely with the growing network of community biotech labs across the country and the globe. These community spaces are enabling everyday citizens to experience and explore biotechnologies in new and innovative ways, helping to educate and demystify a technology that until recently had only been accessible to those

privileged enough to attend a university. I'd like to encourage the FDA to explore utilizing these spaces as part of their outreach and engagement efforts. I'd like to thank you again for allowing me to talk briefly about the GES Center and we look forward to providing a more detailed submission for the official docket.

MR. WALDROP: Thank you. Any questions?

MALE VOICE: You mentioned the public perception study in progress.

DR. KUIKEN: Yes.

MALE VOICE: Have you completed any public perception –

DR. KUIKEN: The survey is in the field now and they've done some focus groups on it, and so they're starting to analyze some of that data, and so they'll have a sort of – a preliminary sort of report on that. They're going to analyze that this December.

MALE VOICE: Are there others one, though, that you've done previously that have already been wrapped up?

DR. KUIKEN: Not around gene drives

specifically, no.

MR. WALDROP: Well, thank you all very much for your comments thus far. I think we're going to take a 20-minute break and then we will rejoin back in this room. Let's see, time, so it's now 9:50, so 10:10 we'll come back here. If anybody as you were sitting here thinking maybe I want to make a public comment, please contact Juanita Yates during the break and she'll make sure she gets you on the list and then we'll see you all in a bit. Thank you.

[Break]

MR. WALDROP: Let's go ahead and get started again. Thank you all very much for being here. We did have one other person that wanted to provide public comments, Preston Peck.

MR. PECK: Thank you for holding this public meeting today. I came and did not intend to speak. I came mostly to listen. But upon listening to some of the other comments that have been made and kind of the direction of this meeting and the willingness for FDA to seek input from the public, I felt compelled to speak. So, these are kind of some general thoughts

that I've had about the various comments that have been made and kind of the direction of this conversation that I wanted to provide.

My name is Preston Peck. I'm the policy director with a 501(c)(3) nonprofit based in Raleigh, North Carolina called Toxic Free North Carolina. I've been with that organization for several years now. Our organization is 31 years old. We were founded through a collaboration of a couple different people, one of which used to work for our North Carolina Department of Agriculture back in 1986, was finding large quantities of groundwater and well water contamination from pesticides. The gentleman went to his supervisors within the Department of Agriculture. These concerns were dismissed by the Department of Agriculture even though he was very well versed in pesticides and health effects of pesticides. He ended up going to the media about this and taking on the Department of Agriculture for suppression of information and ended up winning that lawsuit and founding our organization to bring awareness around the adverse effects of chemical intensive agriculture but also pesticides in

homes and schools as well and their prevalent use in our society.

Our mission is to engage North Carolinians in the transition to a toxic-free society through initiatives that promote human and environmental health.

I also, in addition to being policy director at Toxic Free NC, I sit on the Pesticide Program Dialogue Committee with the EPA through the Office of Pesticide Programs. But today I'm here representing our organization and not that committee.

I wanted to kind of, I felt like some of the comments that have been made are kind of a stretch away from the general questions that FDA provided and more so kind of philosophical questions about whether we should be using GMOs or not using GMOs. So, I'm going to try to stay connected to those questions as well as possible.

But so far as the first question on specific topics or questions or other information that consumers would find most useful, I firmly believe that information regarding whether products contain

GMOs would be a useful tool for consumers to provide more information. Now whether those GMOs carry a negative context with them is kind of irrelevant to me. I believe that it's something a more informed consumer can make better decisions. If they have a negative connotation with GMOs, then that's the information that they have chosen to read and chosen to pursue, and that is up to the individual and that is not up to government or any other person to decide that information for them. An informed consumer can make that decision themselves.

I know that many states across the United States, before I was in North Carolina I was in Vermont, have spoken up about this issue and many of their concerns to be squashed by special industry interests. So that is concerning to me, that even though people speak out and have a strong desire for this, that special interests and money trumps that many times, which I think we've seen a lot.

Another thing that I wanted to bring up that I think that I've heard many people kind of echo today, many of the farmers, and I thank the farmers

for being here. I work with various types of growers across the state, is this kind of idea that with GMOs we have seen a decrease in inputs, being chemical inputs or other kinds of inputs as well. I hear that, and from a kind of theoretical standpoint I hear where that's coming from. I would like to see a lot of that information. So far as I've seen are only estimates from EPA or other kind of organizations that have looked at that. I think the amount, the exact amount of chemicals used in agriculture across the United States would be very useful for consumers to gain an understanding of kind of the breadth of this problem, or reliance upon chemical-intensive agriculture. So, I would invite any of those individuals that have said that to come speak with me afterwards and direct me to where this information is, besides estimates or kind of vague descriptions about how much chemical use we're using. And even at that, we're talking about hundreds of millions of pounds of chemical usage across the United States, and North Carolina, too. So, I would love to have that conversation.

I've also heard some representatives come up

and speak about the value that consumers place and the general public place on academics and scientific institutions, and I think that's true for some. I do. I think that's not true for many as well. I think that that's evident by several factors, I think one of which, the National Climate Assessment that just came out was pretty conclusive in that humans are more than likely causing a lot of issues related to climate change. Yet a vast amount of the population still refuses to believe that that's happening or that it's human-induced, so I think that that's a prime example of how, yeah, sure, there are some people out there that really value that; however, there's many people that do not.

I think if government really wants to reach consumers, then you have to meet people where they're at and really understand who you're speaking to in a way that is not too, maybe academic in its language, or that it needs to be something that is relatable to them, and in a way that they can understand.

Which kind of gets to the second point of the second question, which was – I don't want to

paraphrase. Currently how and from where do consumers most often receive information on this subject? Someone who spoke earlier described a lot of people don't have the time nor the energy to wade through all these academic articles, and I agree with that. It's my job to do a lot of that, so I try to do that and distill that information for our supporters as well as the general public that we work with, or growers or farm workers that we work with as well.

But I think that a lot of people that I speak with get information about this, some from the internet, sure, but also some from peer-to-peer, just kind of having conversations with people about this. And many people are opposed to this just from – opposed to GMOs or the chemical usage that comes with them, kind of from lived experiences and having conversations about kind of, is this the way that we should be cultivating agriculture in the United States.

I've heard a lot about we have – I've worked with the chemical industry, spoken with them on numerous occasions, as well as big agriculture across

the U.S., and one phrase that always comes up is, we have nine billion people to feed and we have to feed the world. However, poverty and hunger still exist and has continued to exist even in the wake of GMOs. I would contest that with not only do we need to feed the world, but we need to provide nutrition for the world, and looking at things like nutrient density, as well as, my personal perspective is I don't think we have a hunger problem so much as a distribution problem. There's economic poverty, there is corruption within foreign governments, there is flooding of aid to these foreign governments that saturate markets, pushing out local growers, which is a major problem. We've seen that in Haiti. We've seen problems with that in Puerto Rico. We work with growers there as well.

So, I think that that's important for consumers to know because the way they get a lot of their information is peer-to-peer. So, if there can be some kind of measure made by FDA or EPA, Department of Agriculture to kind of come at this collaboratively, which I commend you on as well. I always think

interagency work is great work, and you should be working together, so I think that that's fantastic.

So, I think in conclusion I would answer kind of the third question about how people can reach with the scientific information is have a strong understanding of where people are coming from, the geography and culture in which they live, and try to tap into those resources, and step back maybe from so an authoritative perspective, but rather a kind of community-based perspective, because a lot of the information that FDA seeks lies within the communities in which these people live. So I think that there can be good on-the-ground outreach.

I think that this is a good first step. This is not the answer, because many people that are in this room I suspect are paid to be here, so I think it's difficult. I know that I've navigated the comment web on EPA before, or FDA, can be rather confusing at times for individuals and also presumes that they have access to internet as well, which in many rural counties in North Carolina, many people do not. So, I think that there can be efforts there, and I hope that

the FDA and EPA and Department of Agriculture uses this money in a very effective way. Thank you for your time and thank you for allowing public comment and conducting these meetings today.

MR. WALDROP: Any questions?

MR. PERRY: Just one comment. I can probably get you some information on the chemical usage and then the trends over the past several years if you want to leave me your email.

MR. PECK: Great.

MR. WALDROP: Thank you. So, we do have some time left on the agenda, so I did want to open this up now to, if anybody else has any comments that they wanted to make, as you were sitting here thinking, or maybe you want to make additional comments if you've already given comments. I just wanted to make sure we have some time for anybody that wants to do that. So, if you do, please just step forward to the mic.

CLARIFYING QUESTIONS AND FOLLOW-UP ITEMS

Okay. Everybody feels like they've had their say? Then we'll move to the next portion of the agenda. I wanted to turn to our federal government

officials here at the table and see if they have questions, clarifying questions for the audience or anything as they've been sitting here thinking about your comments, if they have anything that they would like to ask the audience and try to get some additional feedback on.

Before we do that, I would like to ask our participants online if they have any clarifying questions for our government officials here in the room, you can please submit those questions through the webinar and we'll go through those and share some of those questions in a few minutes, but first we'll turn to our federal government officials. And if folks want to respond, please just come up to the microphones here in the center so that we make sure that we can hear, the folks on the webinar can hear your responses, and we can get them for the transcript. So, I'll turn to any folks, and my colleagues here.

MR. JHEE: Preston, can you hear me? I liked your idea about being able to take a step back and reach out more at the local level. I would call it

more the grassroots or the holistic level in terms of this Outreach and Education Initiative. Could you suggest any alternative approaches? Hearing from you describing the way we're here sitting here in this public forum today, and it may not be accessible to many of the other people that we need to conduct outreach to. So, what would be some suggestions that we could capture on how to move forward and take back home with us?

MR. PECK: Thank you. I appreciate that you're interested in this, and I think that there's a lot can be done. As you know, the Federal Register is useful insofar as that it provides information. Very difficult to navigate, and very long, very verbose. So, I appreciate your willingness.

I think a lot of the times -- so I'll give you an example. I'm working with a community member out at Carolina Beach right now that suffers from, she's a three-time cancer survivor. Her neighbor uses extensive fogging and fogs with Sevin as well as uses some farm grade lawn treatment, of which he's been cited a couple of times through our Department of

Agriculture. But she is speaking with our pesticide board in a couple of weeks about their education and outreach efforts, and what she can do as a community member to help to promote a healthier community, increase awareness around pesticide application, the adverse effects on people that are already susceptible to that.

And I know EPA does a lot with pushing a lot of their information towards state lead agencies, which I think could be a valuable tool in whatever lane, I guess, you are in. You're with Department of Agriculture, correct? Yes. So maybe USDA could work with our Department of Agriculture and help push out information about these meetings to growers or nonprofit organizations like Toxic Free NC that may work on these, that can help spread that information, collaboratively work together just to get the information out there. And we could provide feedback on reasonable times as well. It may not be times that are convenient for folks, and that's just kind of the way it is.

I come from a background of community

organizing. Many late nights of meeting at 7:00 or 8:00 at night because that's when people can meet, and sometimes you've got to have food there, and you've got to have childcare there. There's all these kinds of barriers that people face in the realities of their situation. And I think it's great to hear from people that are directly involved with the industry and directly involved with the growing aspect, but if you really want community input, then I think you've got to meet people where they're at. So, I would welcome, I'm happy to give you my card and we can kind of brainstorm more ideas. But I think starting with state lead agencies making, perhaps pushing information through us or bigger organizations like Farm Bureau, someone like that, that's very well connected across the state. I think I saw a representative from Farm Bureau here earlier. I think that would be half the battle, just getting the information out there, at a time that could be conducive to people showing up.

MR. WALDROP: Other questions from our panel?

MR. PERRY: I would say one thing that I've noticed here in this discussion. It does seem like

there's a pretty significant gap that could be bridged between the technical and scientific information that the regulatory agencies put out, and the kind of information that the public, most typical consumers, need.

It makes me wonder if trying to generate some sort of document, rather than just putting out risk assessments and decision documents that, again, are very technical, trying to generate something that puts those documents in context as far as what they mean or to make them more relevant to most, to a larger audience of people. Because it can be confusing when you're trying to go through the Federal Register or something like that, and there are so many, multiple documents, and you don't know where to start, you don't know where to finish, and very few people are probably going to read through and understand a lot of the details that are in those documents. I know I wouldn't have if I didn't work for the Office of Pesticides Programs.

I just think that's one theme that seems to have occurred in a couple of people's comments here.

Maybe it's something we need to think about. More of a comment than a question.

MR. DIETZ: One of the questions that I had, I think a few folks mentioned social media. And I'd be interested either in written comments to the docket or comments today, of folks who are aware of social media initiatives that have been aimed at just providing education, sort of like what we're doing today. I know that one commenter provided some examples. If folks are aware of other examples, we'd certainly be interested in that as well. Thank you.

MR. WALDROP: Any other comments here from the panel? Maybe we'll turn to the folks on the webinar. Ayma, any questions there? Nothing yet? Okay. We'll wait just a minute. Any other comments that folks would like to make? Questions? Clarifying questions?

[Inaudible audience member]

MR. WALDROP: If you don't mind just coming to the mic so we can capture your comments.

MR. CHAPMAN: I'll just add real quick on the social media part of it, one that comes to mind, I

believe her page name is Dairy Kerry. She's from up in Wisconsin. Also from the Midwest, Peterson Farm Brothers. It's actually a family. Both of those do a very good job looking at different aspects, but they both encapsulate a lot of different parts of the agricultural sector. It's not them pushing their opinion or their viewpoint; it's them pushing reality as far as what goes on day in and day out. They're both on farm, employed through their farm, not paid by other organizations, just such as I am today. I know, no slight on you, Preston. You mentioned a lot of people are paid here today, but I'm not. I'm losing money being away from my farm to be here. Just such as those two I mentioned, a lot of times they're more than happy to go to events and host events that stem from their social media outreach. And they're actually losing money just to portray truth, not to push that, hey, GMOs are good, we need this, we need that. It's just they're portraying the practices that are put in place.

And something that myself and Mr. Duvall discussed earlier, I mean there are so many examples

now. I mean, I could stand here and go through them all day, but for time's sake I won't, of how the biotechnology has benefitted the agriculture industry. I know, Mr. Perry, you mentioned being able to provide the records for the decrease in pesticide use. And you know as well as I know, any farmer using pesticides have to keep records year in and year out or they don't have a pesticide license. So, from a personal standpoint, I can say there's very well documentation of that, the decrease in use. And they portray that through their social media. I mean they're more than happy to show anything that they're legally able to show, that shows how it is benefitting the consumer, as well as their operation.

Like Mr. Duvall and myself talked about different varieties of corn. A more conventional variety of corn, whenever we experienced a tornado two weeks ago, would've been flat on the ground. We had a neighbor, their corn was flat on the ground. My father actually harvests for them, and I would venture to say they maybe, maybe saved 40% of it at most, and that's a big loss, a huge loss. To where another neighbor has

a different variety of corn that is still standing, not a lot of difference in it, but the biotechnology that is behind that plant has allowed it to continue to stand. So that's where now we can provide that as a food source for whoever, whatever, whether it be human consumption or animal consumption, because the biotechnology has allowed it to stand while also the farmers not losing their bottom line by having that product on the ground and wasted therefore.

So, going back to the social media, those two individuals do a very good job of portraying things such as that, and they've had a lot of outreach because of it. That's two examples that just quickly come to mind.

MR. WALDROP: One question I'd like to ask the audience. We heard from several commenters about a potential disconnect between consumers who purchase food for their families in the grocery stores and farmers, and not really understanding sometimes where, how food is grown, where food is produced, those sorts of things. As one commenter said, we can't bring the entire country to a farm, but what are some ways that

you think might be effective in just helping people understand where their food comes from, how it's grown, how products come to market and those sorts of things. Any thoughts on that in just terms of kind of maybe trying to bridge that gap a little bit?

MS. RICHARDSON: I would go back to my initial comment on the state fairs. I mean, years and years ago, I'm talking a long time, 30 or so years ago when 4H and FFA, Future Farmers of America, were very active in high schools. It was common to have clubs and the kids worked quite a bit on projects during the year. And then at the county fair or your regional fair or state fair, you often got to talk or present, and it was really good way to connect with just general society about what you did on a farm, and get to see animals up close, and really understand them.

I think that's changed a lot now. A lot of the focus is on the rides and things like that. If you go to the fairs, they don't do that anymore. Agriculture has really pushed to the back, and that was really the point. And I think we have to find those ways to connect with people, because they're

going to go there anyway. So, if you have them kind of there, and you can find opportunities to interact with them, and let them understand this is where your products come from, this is what we do, I think those kinds of opportunities are the best way to do it because you have a captured audience.

MR. WALDROP: Great. Thanks.

MS. WATSON: I think one good thing that we've seen over the last five or ten years, I remember maybe 20 years ago if you were looking to do a farm tour, it was not always easy to find farmers who were opening their doors for the public to come in. And now I think we've seen a huge shift in that, and farmers have really stepped up to the plate, and it is pretty easy if you live in reasonable proximity to some farmland to find farmers who are willing to open their doors and do tours, which is great.

But I think one of the really positive things about social media in today's age of communication is that we can do virtual farm tours, and we're trying to do more and more of that in dairy, whether it's for placement on social media channels or

we're also working with Discovery to do farm tours so that kids coming along who can't get to, maybe in an urban environment, can actually go through an entire farm. So, I think that using some of the technologies that allow people to at least feel that they're being on a farm, and see it firsthand is an option that would be a nice possibility.

MR. WALDROP: Thanks.

MR. PECK: I think that there's lots of opportunities here. I think that some that were presented, state fairs, social media, are all good ones, too. I think that a greater issue is just the sheer number of people that grow now which has decreased to what, one or two percent of our population? It's hard to connect with people when it's that small of a population. So I would encourage promoting small farm programs, small grower programs, new and beginning farmer rancher programs, increasing funding for that, to get people involved in agriculture, either as a grower or as a market, someone that can help bring the products to market. Because it's not only about growing food, as you know,

but about getting it to market as well, and creating those streams where people can get their products to market.

That's what our organization tells people all the time, is the best thing you can do regardless of whether you're buying organic or conventional ag, is know your farmer, talk to your farmer, understand what practices they use. And many times, they do what consumers want, because they're trying to sell the product. So, I appreciate the farmers that are here, and Bryant, you too, and I know it's challenging to get here on a day when you're supposed to be at work. So, I really appreciate growers taking time out of their day to be here.

But I think that if we want to really connect with our food again, we've got to go where people are going, and unfortunately, they're leaving rural areas going to urban areas right now. So urban agriculture, promotion of that can be another way. And increasing the amount of people involved in farming. And then you're going to definitely increase your chance of people knowing growers, understanding where

food is coming from and can have a greater idea of how we cultivate food in this nation.

MR. WALDROP: Great. Thanks for your comments. Yes.

MR. DUVALL: Yes, I'd like to address, earlier I mentioned Common Ground, and U.S. Farmers and Ranchers Alliance. A couple more that come to mind on a state issue, the Illinois Family Farms is one that kind of is social media savvy. And then on a younger scale is Farm Bureau's Ag in the Classroom program that targets mostly fourth graders, but certainly the application would be for all ages.

And then one other comment that I think is probably important to comment on that perhaps would be valuable to you to present as well is that the idea that these traits or these are just invented and then accepted at markets.

If I'm not mistaken, it takes an average of 15 years for a trait, once it becomes developed, before it actually reaches the marketplace. So, I think that would be important to point that out, that there's literally 15 years' worth of testing before

these traits are commercialized.

MR. WALDROP: Thank you. Ayma, anything from the web?

[Inaudible response]

MR. WALDROP: Okay. Any other comments that folks would like to make? Anything that you've been thinking of?

DR. CREASEY: If I may. I also think it's important to allow society to recognize how genetic engineering has touched their lives in general, not just the food they eat. For example, wallpaper paste, starch, the major component, is genetically engineered corn. Same with bioethanol. Or the clothes we wear, cotton. Sweet potato is infected by agrobacterium tumefaciens, the same agrobacterium we use in the lab to transfer genes to plants. And yet everyone's not boycotting sweet potato or yams I guess.

In Europe, especially in England in the mid '90s Flavr Savr tomato was actually outselling tomato products in Sainsbury Supermarket. My friends couldn't buy it because it wasn't even on the shelves at that point when they went to get it.

So, I just believe there's other information, maybe not just the hardcore science and data, that could more allow an easier dialogue for people to realize just other aspects of how this technology is in their lives already, already around them already. Thank you.

MR. EDGE: Benjamin Edge. I'm a former small grains breeder with Pioneer Hybrid, and then also Clemson University.

As far as the social media aspect, I'm involved with a couple of Facebook forums, GMO Skepti-Forum and Food and Farm Discussion Lab, where we have a combination of academics, industry reps, farmers and lay people that are just interested in science that look at current events, news articles, and scientific papers, discuss them, debate them, and then bring scientific evidence to present to people so they have a resource to talk about GMOs and biotech in general. The Food and Farm Discussion Lab is more about farming in general and also food nutrition.

As far as ways to get information out to the public, one thing that's probably overlooked, and also

suffers from lack of funding, would be the Extension Service. That's their job is putting information out to the public. So that would be one avenue. Thank you.

MR. WALDROP: Thank you. Other comments or clarifying questions?

Ayma, last chance on the web. Okay, thanks.

FEMALE VOICE: I just briefly want to say if there's any way we can resurrect the whole notion of labelling and do it on a federal label, not with a bar code, but just put the words on the label so that people can make their own informed choices based on what all these people are saying, whether it's science that's bought or science that's done, by someone who's credible. Put it on the label and let people know, because it's so difficult to know now what's genetically modified and what's not. And there are people that don't care, and there are people that do care. But it's also, it would make a big difference in tracing, traceability problems. If something does come out on the market and people do get sick, there's no way to trace it back right now. But if it's on the label, we'll know, and we can do better studies. Human

studies instead of just animal studies.

MR. WALDROP: Thank you. Other comments or questions?

Going once, going twice. Any last thoughts from the panel?

WRAP-UP

Okay. Well, thank you again very much for your participation, for your willingness to come here, take time off work or to take time from your days to be here and participate in this public meeting. We greatly appreciate your comments. As I said, we will take those into consideration as we begin to develop and implement this Education and Outreach Initiative.

A couple of quick reminders for those of you who do want to submit written comments. Please do so via electronic submission or written submission. Due date is November 17th, so make sure you get them in by then.

And then a transcript and a webcast of this meeting will be made available on the FDA's meeting website, so look for that. Once we get that available, it'll be up on the website and you can review parts of

this meeting if you want to.

Again, thank you all very much for coming. We really appreciate your comments and your input, and hope you have a great afternoon and safe travels to all of you headed home. Thank you.

(FDA Public Meeting on Agricultural Biotechnology Education and Outreach concluded.)