FOOD AND DRUG ADMINISTRATION (FDA)

PUBLIC MEETING: AGRICULTURAL BIOTECHNOLOGY EDUCATION AND OUTREACH

Tuesday, November 14, 2017

San Francisco Marriott Marquis

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P R O C E E D I N G S

WELCOME AND OVERVIEW

MR. McKALIP: Good morning, everyone, and welcome to the Marriott Marquis San Francisco. I'm Doug McKalip. I'm with the U.S. Department of Agriculture's Animal and Plant Health Inspection Service. I really want to thank you all for being here this morning with us. I know folks have to leave their businesses and other activities to travel and take the time out to be part of this session, and we really appreciate that you're here. And for those of you participating by webcast, we appreciate your participation as well.

This is really an important session. This morning FDA, along with USDA and EPA, are holding the second of two listening sessions to get your input and feedback on the future of an Agricultural Biotechnology Education and Outreach Initiative. Many of us here in the room were part of North Carolina session in Charlotte last week, and we had a really excellent set of feedback and comments from diverse perspectives, and we're really looking forward to

having that here this morning as well.

Following my comments, we'll have a few brief remarks from my FDA colleague regarding the role of the various federal agencies in regulating Ag biotechnology, and then we'll move into the public listening session portion of our agenda here this morning.

Before we get started, there are just a couple housekeeping and logistical items. We will be here pretty solidly throughout the morning. If folks get hungry and need food items, just go up the escalator one level to the lobby area and you'll find up there the Mission Street Pantry, which has a variety of food items.

Also, if you need restrooms, on the opposite side of the elevator banks on this level are where the restrooms are located.

Several of you have asked about Wi-Fi capability here in the hotel. I do know there is Wi-Fi available in some areas and not others. Please see the Marriott hotel staff if you have any questions about accessing the Wi-Fi system and where that is available

to you.

Media. If you are with the media and you haven't already registered at our registration table, please do so. That will help us know who you are and it'll help us know where and how to interact with you. If you have any logistical needs or questions, please see the FDA staff that have a blue ribbon on their name tag. This indicates that they have answers to questions and can help get you what you need and make sure that you are in the right place and locations.

So, why are we here this morning? In May of 2017 Congress tasked the FDA in coordination with USDA to provide consumer outreach and education regarding agricultural biotechnology and biotechnology-derived food products, and this includes animal feed as well, through the publication and distribution of science-based educational information on the environmental, nutritional, food safety, economic and humanitarian impacts of biotechnology. So that's really the mandate. That's why we're here this morning. This process is beginning, and we want to get feedback and input from you at the beginning on what this might

look like.

You'll notice I use the phrase biotechnology. That's the scientifically, I think, widely accepted term. It's what we use. It's what appears in the Congressional legislation, but we recognize that folks use a variety of terms to describe this. So you may refer to it as genetic engineering or GE. Others of you may refer to GMO. For the purposes of this morning, any of those terms is just fine. The most important thing is that we get your feedback and input. So we're not going to fixate on the exact terminology that folks use to describe the technology. Because really your input is really the most important thing to help drive the future of what this initiative looks like.

FDA published a Federal Register notice that really tries to focus the discussion, that can help impact the process to most. These three questions are the focus of this listening session and of the feedback that we need.

Number one: What are the specific topics, questions, or other information that consumers find

most useful and why?

Question number two: Currently how and from where do consumers most often receive information on this subject?

Number three: How can FDA in coordination with the USDA best reach consumers and science-based educational information on this subject?

So those are really the three questions that serve as the focus for our discussion, and again, your comments on those will help best impact the process that we have moving forward and on implementation of this initiative.

I have a list of those who have signed up to provide comments to us here in person this morning. We may have some additional time at the end of the session, and if you haven't signed up to give comments, but if you decide you would like to, you can sign up during the break that we'll have, and Ms. Juanita Yates would be your point of contact. Juanita, can you stand so folks know who you are?

Great. Thanks. See Juanita if you haven't signed up to provide a comment but would like to, and

again, if there's time and a slot to do so, Juanita can help get you signed up to provide comment.

Each commenter will be limited to ten minutes. That will be a lot, given the number of speakers that we have registered to provide input. So we'd respectfully ask that folks please keep to the ten minutes and we will give you signals if you've reached the limit of that time limit.

There is the opportunity to provide written comments as well. So if you weren't able to say all that you really needed to or wanted to in ten minutes, or if you choose not to speak in person, we are accepting written comments. Hopefully the slide there provides the logistics of where and how to send those in. I would note that all comments are due to us by November the 17th, so we'd like to get those in as soon as possible.

A transcript of this morning's proceedings will be available as well in just a few weeks, and the video from the webcast will also be available for folks to take a look at as well.

Your comments are important because they

will help form the development of this Education and Outreach Initiative. Your comments are going to help us determine what the topics are that are covered, the format of any materials that are developed, and the methods that are used to provide the education and outreach to the public.

In addition to these listening sessions that we've conducted, FDA is also going to focus and review current research related to consumer attitudes and perceptions regarding Ag biotechnology. FDA will also be conducting some focus groups and research to test out education concepts and messaging as well. That will be done in coordination with the three agencies, with USDA and FDA as well, which is the perfect time for me to introduce my colleagues that are here at the table.

Representing the Food and Drug Administration, Dr. Ritu Nalubola. She is a senior policy advisor in the Office of Policy at the FDA.

Also Alan Reynolds who is the Biotechnology team leader at the U.S. Environmental Protection Agency. We're really happy. This has been a great

partnership effort for the three agencies to coordinate on.

I'd now like to turn the podium over to Dr. Nalubola to walk us through some brief remarks on how the government currently regulates agricultural biotechnology. Ritu.

FEDERAL GOVERNMENT'S ROLE IN REGULATION OF AGRICULTURAL BIOTECHNOLGY

DR. NALUBOLA: Thank you, Doug. First of all, good morning everyone. I want to echo Doug's comment just now. Thank you for your interest. Thank you for being here. This is, as Doug mentioned, the second of two public listening sessions that we are holding. The one in North Carolina was held last week. I'm really looking forward to your input today, and also comments that will be coming into the docket.

I will give you a very brief overview of the federal government's role in the regulation of biotechnology, products focusing on agricultural biotechnology. And that's simply to provide some context for who we are, the three agencies, and what it is that we do in this space.

Biotechnology products in the United States are regulated primarily by three regulatory agencies. Those are the Environmental Protection Agency, the Food and Drug Administration, and within USDA the Animal and Plant Health Inspection Service. You have representatives from each of our agencies here today.

Each of these agencies has different roles and responsibilities, and we implement the statutory mandates that are given to us. For example, within EPA they are responsible for the protection of the environment and human health. EPA regulates pesticides and also pesticide chemical residues that may be present in food. FDA regulates a wide variety of products, including we look at the safety of food for both humans and for animals, and also the safety and effectiveness of human and animal drugs.

APHIS, the Animal and Plant Health Inspection Service, is responsible for making sure or protecting agriculture from pests and diseases and they regulate biotechnology products that may pose a risk to animal or plant health. Taken together, these three regulatory agencies help ensure that products of

biotechnology including agricultural biotechnology are safe and lawful.

We work together, the three agencies, under something that is referred to as the Coordinated Framework for the Regulation of Biotechnology. This was a document, a framework that was first established back in 1986, another update in 1992, and most recently updated in 2017. It describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology products.

There are some guiding principles that were first elaborated back in ’92, and again reviewed and reiterated most recently in the 2017 update. I will highlight just a few guiding principles here. The Coordinated Framework itself does not give new authority to the agencies, but it notes that agencies will regulate biotechnology products using our distinct statutes and regulations to ensure the safety of these products for their intended uses.

The three agencies strive to cover the full spectrum of plant, animal, and microorganisms and their products derived using biotechnology. And we do

endeavor to operate our programs in an integrated and coordinated fashion. Within the three agencies we conduct our evaluations of products based on the science and the evidence related to those products. We look at the product, its characteristics, its intended use, and the environment into which it is introduced in determining whether and what potential risks may be associated with those products for those intended uses.

Taken together, the Coordinated Framework really seeks to find a balance between adequate regulation for the protection of health and environment, and safety of products, and sufficient regulatory flexibility so as to not stifle innovation.

Again, today we are here really looking for your input and your feedback on areas related to agricultural biotechnology, specifically looking at the three questions that were posed in the Federal Register notice, and the ones that Doug highlighted earlier.

Today's meeting is an opportunity for us to hear from you. We recognize that there is a range of

views and perspectives on this issue, and we are seeking your feedback early in the process of developing this initiative, and so that your feedback can inform us as we develop and also implement the initiative consistent with the direction that was given to us by Congress.

So again, I thank you for being here, and look forward to your input today at the meeting, as well as the comments that will be submitted to the docket. Thanks.

MR. McKALIP: Thank you, Ritu. Really appreciate those remarks.

STAKEHOLDER INPUT AND COMMENTS

MR. McKALIP: We're going to move into the public comment portion of our agenda here this morning. We'll work down through the list. As you are called, if you would please, you can use either of the two microphones located here on the floor. We ask that you do use those microphones. Those will go directly to the transcription folks who will be making a recording and a full written transcript of the proceedings today. It will also allow our cameras, for

those who are tuning in by webcast, to see you from the cameras here in the room. If I mispronounce anyone's name, I apologize. I'll do my best given the written list that I have. I would also note that all of you have folders as well, and those folders contain not only the list of participants here at the meeting, but also the Federal Register Notice as well. So again, if you haven't commented and choose to do so in writing, that is an option as well.

So I'm going to call up Daniel Westcott from the University of California at Berkeley to be first. Again, we appreciate you keeping to ten minutes. We will signal you if you run over. Thank you. Daniel.

MR. WESTCOTT: I've gotten a written-ish kind of statement that I may veer around. Feel free to stop me at any time.

Hello. My name is Daniel Westcott. I'm a graduate student in the Plant and Microbial Biology Department at UC Berkeley. I study that first step in the food chain, photosynthesis, how plants use sunlight to grow. Before graduate school I earned a degree in science education, and before science

education I worked on an organic farm.

Now that I'm in graduate school I continue to do outreach and practice science communication through a student group on campus called CLEAR which stands for Communication Literacy and Education in Agricultural Research. If you were to draw lines between agricultural biotechnology education and outreach, I would find myself squarely at their intersection. I feel uniquely qualified to provide comment on the topic at hand.

So buried deep in this $1.2 trillion appropriations bill we find $3 million set outside for outreach and education regarding agricultural biotechnology. It's a tiny fraction, 1/400,000th of the budget, but it is rightly raising concerns. Many of the engaged citizenry here will wonder how such a line made its way into this gigantic bill, and many of the engaged citizenry here are right to be skeptical of the motivation of the authors of this part of the bill.

Consider the phrase consumer outreach. That phrase is likely troubling to many people here. It

implies that the government is a marketing firm, which it isn't. We're not consumers of government; we're citizens. We aren't consumers of government; we are the government. So, educating the public on the risks and rewards of agricultural biotechnology is a worthy goal, one which I wholeheartedly support. However, I feel that clarifying the agencies' motivation here is a critical step in achieving this goal.

The current administration has done little to build trust among the public, and $3 million of taxpayer dollars towards an outreach effort has raised concerns that must be addressed if FDA and USDA want to make meaningful progress on this effort.

For too long the conversation around agricultural biotechnology has been stuck. There are those who think that genetic engineering can be safely used to develop beneficial new crop varieties, and there are those who adamantly oppose any such use of genetic engineering. The dogmatic approach represented by those opposed to genetic engineering has resulted in a tribe of absolutists, absolutely not, no matter what, no matter the possible benefits. I've read the

comments for this docket and others on related subjects and the general perspective that's best represented there is no GMO's, not now, not ever. This view will only be reinforced if we fail to address those concerned in a forthright and transparent manner. And I'm really glad that FDA and USDA have the opportunity to do that.

My first recommendation to the agencies in this effort is to reach past the established dichotomy surrounding agricultural biotechnology. Those opposed to biotechnology in agriculture have valid arguments and concerns that should not be ignored. They point to ways of feeding a growing population in a changing climate such as organic and regenerative agriculture. These techniques have real merit and should not be dismissed. They can potentially sustain soil health over long periods of time, and maybe longer than the large-scale agricultural methods and potentially have fewer negative impacts on the environment. But that doesn't mean that there isn't a place for biotechnology in these systems. Regenerative agricultural systems can be used in conjunction with

biotechnology. Currently our regulations don't allow for such thinking. We've got an organic system, a definition of organic that completely excludes any crops that are generated by using biotechnology. This seems to me in conflict.

So you could and we do use biotechnology to develop crop varieties that require less fertilizer, produce higher yield and are less susceptible to disease. This is absolutely compatible with environmental goals of those who want to advocate regenerative agricultural techniques, so however the current absolutism prevents us from combining the best scientific and holistic approaches to meeting the growing demands on our agricultural system, the result of this false dichotomy is that the organic label has become an entrenched business that's happy to charge a premium on their products without addressing the long-term sustainability goals of the organic movement.

On the other hand, those who aim to generate new crops using biotech need to be deep-pocketed, large companies if they plan to navigate the complex regulatory burden enacted due to public pressure and

fear. There are economic interests on both sides of the debate who benefit from confusion and controversy. There's an absolute need for public outreach and education on this topic and I'm glad that it's happening.

As FDA and USDA move forward with this effort, I encourage these agencies to be considerate of the deep-seated values that people bring to this discussion. Those opposed to using biotechnology in agricultural settings are basing that opposition on the deeds of large agro-chemical companies who were unresponsive and at times antagonistic to public concern. This has tainted the toolbox of biotechnology despite the positive applications of those tools. Excellent ideas and seeds gather dust in the basement of universities because of unwarranted fear. This outreach must not simply focus on information and science. These are important aspects of outreach; however, this effort must focus on values, risks and rewards.

The values, the students and scientists that I work with are the same as those who are opposed to

the application of our science. We aim to make a better, more stable world for our children, and opponents want the same thing. We start from the same place. This educational outreach effort must begin from our set of shared values and only then should science be introduced, and later a discussion can be had about the risk of enabling or disabling agricultural biotechnology in the face of growing population and changing climate.

In summary, it is critical that FDA and USDA are successful in their effort to elevate the debate of our citizenry on this topic. New tools are coming online that may fall outside of the purview of current Congressional oversight. In my understanding, and it isn't totally thorough, but I feel like gene editing tools don't neatly fall into APHIS regulation, right? But that's a discussion that should be had as you move forward with the new technology that's coming online like CRISPR and gene editing may not necessarily fall into the existing regulations that are there, and we may need a public debate and discussion to force Congressional oversight to provide a new mandate for

these things. So I feel like that would be a productive avenue.

I feel that scientific fact will not be enough to elevate this debate among our citizenry. The risks outlined by those opposed must be addressed. Similarly, the risks of abandoning these techniques must be addressed. The benefits of both technologies, regenerative agriculture and biotechnology, should be presented as synergistic and an opportunity to work from the best science and techniques that we have to meet our growing agricultural demands.

They shouldn't be presented as oppositional. If we are to address the real challenges of meeting the nutritional demands of a growing population and a changing climate, we're going to need the whole toolbox and not any one single tool.

If these agencies would like further resources that can enable the goal of elevating public discourse on the topic of agriculture and food biotechnologies, please don't hesitate to contact our group at CLEAR. We have a number of motivated graduate students ready to engage on this topic, as well as an

established UC Berkeley faculty member who has worked for many years in this subject area.

The last thing I'd like to say is that we take the approach in our group to actually just go out and be a public face for science. We go to farmers markets, we go to bars, we organize events to increase public discussion. We do this without even bringing up biotechnology in agriculture. Usually it comes forward organically. And so instead of coming out and providing lists of facts that will try and convince people with evidence, we first need to humanize the work that we do. And so I feel like that has been effective in just generating conversation and maybe potentially goodwill in this subject area.

So thanks a lot for the opportunity to comment on this important topic.

MR. McKALIP: Great. Thank you, Daniel. Any clarifying questions from members of the panel? We appreciate that. And we want to give everyone a chance to speak, but if speakers are able to stay until the end, there may be an opportunity for us, based on themes that we're hearing, to ask further questions

from folks that come back to the microphone. So thank you, Daniel.

Next I'll call Lynne McBride representing the California Farmers Union from Lafayette, California.

MS. McBRIDE: Good morning. My name is Lynne McBride. I currently serve as Executive Director of the California Farmers Union, representing farmers throughout California. California Farmers Union is a state chapter of National Farmers Union, which represents more than 200,000 farmers and ranchers throughout the country.

California Farmers Union was founded more than 20 years ago, and we represent farmers who grow both GMO and non-GMO crops. We appreciate the opportunity to provide input on the Food and Drug Administration's Agricultural Biotechnology Education and Outreach Initiative. We commend FDA for holding this public meeting today to provide an opportunity for individuals and organizations to speak openly about the GMO issue. We believe that only by engaging in an honest and open dialogue will consumers be able

to make a more informed choice at the grocery store.

I just want to run at the beginning through the three questions that FDA has posed here today and then kind of walk through our policy on GMO over the issues. It's been a continuous source of discussion and debate within our organization.

So in terms of question number one, we believe that consumers would find it most useful for FDA to exercise greater oversight of GMO crops grown throughout the United States. Consumers look to FDA to determine the safety of GMO crops, and through this initiative FDA will have additional resources to closely examine their safety and be able to provide that information to the public.

FDA would provide an objective perspective on the impacts of widespread GMO plantings throughout the United States, and it would again provide additional information to the public, including some of the information that was presented earlier this morning I think would be of interest. It is, I don't think, widely known what the current role is and what this new funding will allow an increased role to be.

Number two, when GMO crops were first introduced in the 1990s, most consumers were not on the internet and able to learn more about the impact of GMO plantings online. Today consumers can find a wide variety of information on the internet and the media about GMO crops as well as countless other topics. Just in preparation for this meeting I did quite a few internet searches, and I hadn't looked at this issue. I thought I thought I was keeping track, but it seems like there's always more and more information on the GMO issue, be it pro or con, and I think it's this – again with this new funding resource there will be a way to more comprehensively look at that.

Through the Agricultural Biotechnology Initiative, FDA could have a greater role in examining the GMO information that is already out there, and again, there's a lot of it; take an objective view about its veracity, and convey accurate information to consumers.

In terms of question number three, we think the best way for FDA to coordinate with USDA to

provide science-based educational information is by reaching out and engaging with consumer groups, farm groups, other stakeholders, to have a comprehensive discussion of the many issues surrounding GMO crops. By establishing a meaningful dialogue with consumer groups FDA and USDA and EPA can listen to the concerns raised by consumers and farmers about GMO crops and work to address these concerns through discussions of current research showing the impacts of GMO crops, and by engaging in additional research that is of interest and importance to consumers as well as farmers who out there using these technologies.

We urge FDA to reach out to farmers to speak about their experience with GMO crops, and work to convey these stories to consumers to provide accurate information that consumers will trust because it's based on science and the real world experience of farmers.

Then I just want to again run through some of our priority items that, again, this has been a topic of discussion within our organization for a number of years. Our priorities include expanding

research funding for public crop breeding programs so that farmers have more varieties to choose from, including GMO and non-GMO crop varieties.

We've long called for GMO labelling so that consumers can make an informed choice at the grocery store. We also call for taking steps to facilitate independent scientific research on GMO risks and benefits, take a more rigorous, independently verified approach to GMO product approvals so that products do not come to market until their risks and benefits are well understood through an objective and non-biased review.

FDA should ensure the safety of GMO products again through independent testing and review. We believe that all data used in the analysis of the health and environmental effects of GMOs should be in the public record so the process is more open and transparent, which will increase the level of trust and confidence among consumers as well as farmers.

Prohibiting government agencies from licensing genetically modified products that are not acceptable for both human consumption and animal feed,

requiring governmental regulatory agencies and input suppliers to ensure farmers are informed of all the potential market risks and segregation requirements associated with the planting of any licensed GMO crops, requiring USDA to continue to research the effect of GMO feeds on livestock, prohibit the sale of seed of pesticide-resistant crops if the pesticides have not received regulatory approval. And in conclusion, we think the public and private research institutions really need to devote resources, and again hopefully this initiative will be a good start towards that, to assess just the overall impacts of emerging agricultural biotechnology on U.S. farms so that all stakeholders, farmers and consumers can make decisions that ensure genetic engineering contributes to sustainable agriculture throughout the United States.

I thank you for the opportunity to comment today.

MR. McKALIP: Thank you. And really appreciate any questions from the panelists.

MS. NALUBOLA: I have a quick question. I

think one of the things you highlighted in your comments is for us to engage more actively with farmers. I think that came up in a couple of remarks that you made. Do you have any specific ideas for things that we should be doing, entities that we should be working with?

MS. McBRIDE: Yeah. I just know that there's been different sort of stakeholder processes that have been established so if there's a way to invite different farm organizations and individual farmers in different areas. I know that's always a challenge when working with farmers is they're usually out in the farm farming. And so, if there's a way to reach out to them, both individually and through their organizations to get those first-hand accounts and stories about their experience with GMO crops, I think those would be really beneficial. And we as an organization would be happy to reach out to our members, and I know speaking with other farm organizations as well. Because I think the most compelling message here is the experience on the farm with be it GMO, non-GMO, or other forms of farming.

MR. McKALIP: Thank you, Lynne. Really appreciate it. I'm going to continue through our list of commenters. If you happen to not be in the room when your name is called, we will come back to you. Next on my list, Douglas Jones with Growers of Biotechnology from Meridian, Idaho.

MR. JONES: Good morning. Thank you for all three of the agencies for providing this opportunity to take public comment and listen to the thoughts of various groups who are interested in this topic area, and we all should be because we all eat.

First let me tell you a bit about who Growers for Biotechnology is, and about myself. Growers for Biotechnology is a group of farmers, and my Board of Directors is scattered from Oregon to Minnesota, so we're not in one local region specifically. The organization was formed because these are people who believe in the use of the technology in production agriculture.

My personal background, I'm just an old Idaho farmer, and I farm in an area of southern Idaho that's all irrigated, that's all row crop for the most

part, and we grow nearly 200 different crops, very few of which are genetically engineered. In fact, in our own farm operation there would only be two things that we would grow, a third in the neighborhood, that would be even available to us to buy that kind of seed. One of the misconceptions is that genetic engineering covers everything in agriculture everywhere.

But farmers make decisions about what they do based on personal beliefs, but also on economics. Farmers are sold on this technology completely in terms of production of major crops. And I say that, and I'm going to give you an example. When genetically engineered sugar beets became available, herbicide-tolerant sugar beets, farmers wanted them badly, and they'd seen the trial plots and they were dying to have this seed available commercially. The first year that was available, 65% of the sugar beets in the United States planted were genetically engineered to resist herbicide. The second year that number jumped to 95% because there wasn't enough seed available the first year. Probably would've gone close to that second year number had there been enough seed.

It continues to stay at 95-plus-percent. The reason is farmers can see they can produce a higher yield, higher quality, less tillage, less inputs, less soil erosion to wind and water by the use of this seed. They make that decision based on economics of business. And the same could be said about the other crops that are predominantly planted with genetically engineered seed today. And there's only a half dozen really.

So those decisions are made for economic reasons, but people who grow those crops also are the consumers. We eat those things. We feed them to our kids and our grandchildren because we understand there is nothing wrong with those products today.

We also recognize that other people have different belief systems and may have concerns about that technology. That's why there's a niche market for people to produce things using seed that isn't genetically engineered, and to make a living doing it. And most of us are completely happy with that. If one of our neighbors chooses to go that route and can make a living, more power to them.

So that's why the acceptance of those types of crops have been so high in the farm community. It's not that some big seed company holds a gun to our head and says you have to buy this seed, because it's extremely expensive. It's because farmers made a business decision that I can spend more on seed, but I spend less on tillage, less on pesticides, and get a higher yield and a higher quality yield at the end of the growing season, and potentially I make a better living doing that.

That's why we accept it. There's conventional seed available, and in our personal operation we did both. We didn't always buy genetically engineered seed that was resistant to certain things. We bought it when we thought the occasion warranted it for the particular place we were going to go or the crop we were growing.

So that's where we are from the farm community. We recognize genetic engineering is just high tech plant breeding. Farmers for thousands of years have saved their best ear of corn, their best seed. That was a form of plant breeding. Not very

scientific, but that was what happened. And we evolved within the last 200 years to being able to recognize that certain crosses of things will produce certain results. That was done low tech on an experimental basis.

Today we have the technology to use scientific labs, electron microscopes, gene mapping, and other kinds of things to produce the outcome we want more quickly, not less expensively but more quickly with more precise results. And today we have higher quality, higher yields, which helps keep the cost of food down.

We reduce the amount of wind and water erosion in our fields. We have a smaller carbon footprint. We have less food waste because of some of the engineered varieties that are out there now that store better, process better, and produce less food waste. We have better nutrition in some of those crops. We use less pesticides. We use less fertilizer, and we produce higher yields and higher quality of crops on less acres than we have in the past.

The agricultural community is sold. So the

problem comes with the consuming community. We are subject to that as farmers because if we don't have anybody to buy something, there's no point in our growing it. So we need to deal with that aspect of the issue as well. And frankly, farmers are not very good at that. We're great at what we do, farming. We're not very good at public outreach, attending meetings, going to political events, and those kinds of things that need to happen to help educate the consuming public.

So how do we turn that around? What do we do to answer the three questions that were posted earlier? I think there's a couple of issues. They really come down to society and education. Because we're so good at what we do, there are a very, very small percentage of our society actually involved with the production of agriculture. And as people have moved away from the farm, generations have passed and they don't have any connection to where their food comes from. They don't have a grandparent or a family friend who still farms, and you went out to the farm for Sunday dinner or something. That doesn't exist for

most people anymore. So we've lost that connection.

And the second thing is we've not done a very good job of educating people about food production, on why we're efficient and why we do what we do. Unfortunately, today's society and particularly on this topic is influenced more by a belief system than by science facts. I say that unfortunately because dealing with belief systems is much harder than dealing with education on facts where you can have a reasonable discussion and say I produce more of this because I use this high tech seed. But if your belief system is that there's something wrong with that seed, that's a harder issue to address. And some of that I think is societal as well, because we have less trust in big companies, and we have less trust in big government, or you folks sitting there.

As a society, that's not everybody individually. So how do we change some of that? I think short term we need to talk about the things I've listed: higher yields, higher quality, less wind and water erosion, less carbon footprint, better nutrition, less fertilizer, less pesticide. Those are

things we know that we do and we can prove statistically. So we need to educate people about that.

Second, we need to educate them about what has been talked about and what you three folks do with your agencies, the regulation, that it is highly regulated already, and will continue to be regulated in the future, much more highly regulated than conventional plant breeding. So people need to understand that aspect as well.

How do we get there? Well, I think short term the education is the things I've just outlined to you. How do we make changes long term in people's belief systems? Belief systems are developed early in life, 20 years and under. So how do we address that? We start with teachers. How do we train teachers? We go back to the universities. How do we work with the universities? We need to work with the colleges of education in combination with the colleges of agriculture, particularly in our land grants.

So I think education is a long term solution. Having used up my time, I will say thank you

for the opportunity to visit with you this morning. Thank you to you and your agencies for providing this opportunity for public hearing.

MR. McKALIP: Thank you, Douglas. Any questions from the panelists? Thank you very much. Next up on our list, Pamm Larry representing LabelGMOs.org of Chico, California.

MS. LARRY: Thank you. Yes, my name is Pamm Larry and I've been involved in advocacy work for labelling of genetically engineered foods. My journey started in 2011 when I began travelling around the State of California to encourage people to have a ballot initiative to label genetically engineered foods and it became Prop 37 and then started a whole cascade of people requesting transparency, honesty and transparency in their food.

This is very much about choice. I know that there are people within the genetically engineered movement that don't want any kind of genetic engineering going on ever at all, at any time, at any point. But the vast majority of us simply ask for choice and for protection for us not having to eat

them if we don't want to. So therefore we strongly advocate strong controls for organics. We also believe that communities, that if they have a large proportion of organic and sustainable farmers, that they have the rights within their communities to make those kinds of decisions, and have a GMO-free growing zones, should those communities choose.

So with that in mind, I would like to talk primarily, what I'd like to focus on is trust, honesty and transparency. To that end, I think you've asked questions. I'll address each of your questions, if my little thing here will behave.

You asked for some simple truths, and some specifics on what people should be told. I would encourage you to be honest about FDA itself, which on July 26th of 2016 wrote an opinion on the Safe and Affordable Food Act, which was the labelling act which we call the DARK Act, Deny Americans the Right to Know Act. You stated in there that the law would not really label most GMOs and that the definition of GMO is not clear. As a side bar I would like to encourage FDA to use the Codex of genetic engineering, and not some new

thing that discounts all the new technologies, or that, because it could look the same in nature that somehow it's not different.

By the way, we in the movement thank you for that. You said some other things, and it gave me a bit of encouragement that there were some agencies at the federal level that might be looking out for citizens and consumers. Thank you.

I would tell people that companies that sell products here in the United States and also abroad formulate healthier versions of those food products overseas, and they are very transparent as to what is in them. They label the genetically engineered things directly on the package. They don't use QR codes or phone numbers which are being proposed with the Safe and Affordable Food Act.

They also are very quick to leave out a lot of things because a lot of the health agencies in those countries are much more strict than our countries are, and our country allows a lot more ingredients and additives than the other countries do. But people I believe in this country have a right to

know that, that we are the ones that are being given the stuff that I consider poison and junk.

Please tell people that there has never been one long-term longitudinal study on the effects of eating genetically engineered foods in the United States. That is a fact. When I say that out there on the road, some people who are very pro biotech will say, well, it's unethical to do experiments on humans. And I am baffled by that logic, that it is okay to feed this to our children but it is unethical to track the effects.

Tell them that one of the only ways that those of us on the ground know about what's really going on with corporations and the agencies is through the processes of Freedom of Information Act and court discovery documents, and we have found out quite a bit this year and last year through those two processes.

Years ago we found out through the, I don't know if it was through FOIA documents. I think it was, that FDA's own scientists were concerned about allergenicity and toxicity in the '90s. We have found out lately that the educational campaign which has

been going on for quite a while is a very well-orchestrated PR campaign that a lot of money has been spent on by Big Food and Big Agriculture, Big Biotech Agriculture, and that if any scientist, we have proof of this, we have documents, that any scientists that come up with any kind of evidence that's contrary to the large profit margin companies, that they are attacked. They are oftentimes vilified, their families. I mean, and it's not just GMOs, it's pesticides and other things, too. Tyrone Hays being a prime example of court documents which show the coordinated, concerted attack on him and his family. So it is not unbiased science that we're being given.

We know quite a bit about glyphosate. We know that a different agency, not yours, thank heavens, but rather the EPA. We know that, and I can't remember his name, didn't have time to look it up, but someone in EPA talked about getting an award for pushing glyphosate through. We know tons about the fact that the manufacturers withheld information, that they out and out lied about stuff. And so why would any critical thinker trust the data? Why would you

guys trust the data they're giving you? I'm asking you this as a human. I'm not really asking for – it's a rhetorical response, but as one human to another, if you have repeat evidence that a specific company or a group of companies is withholding information from agencies, whether here or in Europe, is lying and attacks scientists who come up with differing data, why would you as a human not question the data that you're getting from them?

Tell them also that this kind of activity is not unique to the GMO thing. Pesticide cigarettes. How long were we told that cigarettes were okay? How long were we told that *trans* fats were okay? How long were we told – I mean, people have to – furniture, sugar. Everybody who goes after or tries to raise questions about the safety and ask for true, unbiased, unbought science were labelled as whackos and vilified and attacked. I mean, online it's vicious out there. I don't even hang out there anymore because – and there are a couple of them today I noticed on your speaking list, that really go after people with emotions rather than just science.

And all we're asking for is that FDA doesn't go back 35 years from now, like they did with *trans* fat, I call it the oops factor. Oops. Sorry. We weren't right. Sorry, the data we had wasn't correct. I'm just asking you as a human to look to that pattern.

Please tell them that the poster child study that they put forward, the three trillion meals, and nobody is sick. Billions of animals eating this stuff, 95% of it was chickens that were killed at 47 days, instead of living out their lives. And that there were only a few parameters that were used, one of them being weight gain. And if that was the case, then nothing about toxicity to the body or the organs or anything like that, but weight gain, production, how quickly they got to production and mortality, and at rate. And that if that was the case in this – extrapolated to United States we would be considered the healthiest people on the planet and we are not.

In regards to how and from where do consumers mostly receive information on this subject, we as citizens in this country receive the information

from a variety of sources. We hear things online, in papers, radio, TV, and from friends, family, and trusted others in our sphere. I, and most people that I know, rely on peer-reviewed science and the scientists that actually do that science. And if we don't understand something about it, we ask trusted scientists.

I have a question, though. You ask where do people receive their information. They can receive their information but do you want them to trust it? Do you want to just give them information? It doesn't matter how much information you give them. If they don't trust the information you're giving them, they aren't going to take it in.

If you start calling CRISPR and things like that not genetically engineered, do you think that's going to increase the trust level? I would suggest to increase trust that there be a study done, that this money be used instead of marketing for a very lucrative business technology, that you instead use the money to have a large study done with, if we can get them all in the same room, people like Pamela

Ronald, Kevin Folta, Gilles Séralini, Michael Antoniou, Angelika Hilbeck, get everybody in the same room at the same time. You'd probably have to have bodyguards and filming 24/7 filming. But do a study on the health issues that both sides will trust.

Thank you so much for listening.

MR. McKALIP: Thank you very much, Pamm. And again, if you were not able to get all the way through your written comments, we can take those and put them into the record in total. So thank you so much.

MS. LARRY: Thank you.

MR. McKALIP: Next up, James Allison from Loveland High School located in Loveland, Ohio.

MR. ALLISON: Good morning. Like you said, my name is Jamie Allison, and I teach a high school biotech program at Loveland High School just outside of Cincinnati. My students earn four high school science credits, six college credits from Cincinnati State, and are doing amazing things.

I think I can help you a lot with number three with some things that we're doing in Ohio. Currently one-quarter of my curriculum, so a semester,

is Ag focused. It was not always like that. I'm going to graduate my 13th group of seniors this year, but four years ago I had a rather interesting experience. I have a group of other teachers from the state. We meet one Saturday a month, kind of solve problems, plan capstone competitions, things like that. And some women representing two groups, the Ohio Soy Council and the Ohio Corn Growers Association, invited all of us and any other teachers we wanted to come to some summer teacher trainings, if you will. That night when I went to that teacher training, I skipped the social hour, which for me is a pretty big thing, and went back and rewrote a quarter of my senior curriculum, because I found out that by 2050 with nine billion people on the planet, we're going to have a hard time feeding everybody.

And the other thing I found out about is that right now there are tens of thousands of jobs available for two-year, four-year, six-year degree graduates, and we've got kids out there with training coming out of my programs and the programs at Cincinnati State, and I've got to find a way to get

the information to them. So I went back until 3:00 in the morning rewriting my curriculum.

I can tell you if you want to get this information to the public, we've got to set up a network, a conduited network where you can take the information, get it to the teachers. But my problem was, I didn't know who to talk to. I didn't know where to get the information.

I wanted good information. I wanted it from farmers. I wanted it from the best resources that I could get, but we just didn't have it. This little group of teachers that I manage, we've outlasted two governors, and I think you guys know what happens as soon as a governor is replaced, the whole kit and caboodle gets thrown out. And so my conduits that used to happen up at the state house and I used to know who to talk to, they're gone. So I'd lose 50% of my connections.

So working with these women that have two groups, one called Grow Next Gen, and you'll have Corn Growers Group. And another group that we call Bio Ohio, they used to be the state bio science

accelerator. Now they do just bioscience service organization. We're creating the network. We've kind of said, all right, state, ODE, Department of Education. We're going to stay involved but you change too much. We need stability.

So now what we've created is this network, and our network of six or seven teachers with these little three outreach groups has started to get some mass behind. We've got a little bit of momentum, to the point that Bio Ohio is actually going to absorb us. And as we get absorbed by Bio Ohio, then what happens is we've two really nice companies that are going to come in and they're going to support us, too.

One of those companies is the reason I'm here, and that's Bio-Rad. They knew about what I did from a fellowship I did over the summer with them. And they said, you know, I think you've got a model that people need to know about. The other group is Fisher Scientific, and that's the educational division of Thermo Fisher.

So now we've got some industry behind us. So now we've got all the players at the table, and we're

starting to be able to take teachers, educate them on the needs. If I can educate my students and get them excited, that excitement takes place at home. And when a kid comes home from school excited, then the parent gets excited.

Now granted, I'm just in the baby steps of this. Four years I've been doing the Ag thing in my classroom, but what ended up happening was pretty remarkable. The first year I threw the two quarters in, all of a sudden two kids immediately take off and go. One of them is studying Ag Science at UK right now in pre-vet. She's coming back in two weeks as an ambassador for that entire program to talk to my kids, and she wants me to get her up into Columbus with some of my other colleagues.

Last year I graduated the first group that had Ag influenced into all of our labs, just the application. So, hey, if you're going to do this lab, where does it apply in Ag? Got four kids that took off last year. This year I've got a smaller group of seniors, half of what I had last year and I've got three out of 22 that are taking off and already

looking at Ag.

Networks are what's missing for communication. I realize that it's kind of hard to visualize with all the internet and everything else, but it's so hard to know who to connect with. In a social hour at a Bio Ohio function, I can go and I can meet a scientist who's like, hey, I'm working on this. I'm like, wow, I've got a student really interested in that. Would you be interested in letting them sit with you for an hour? That'd be great. And the connection is made. And it's all about relationships.

So, what do you want us to know? Tell me. Tell me. I'll teach them. All the teachers will teach them. Where are we going to get the information? It's out there. We just got to make the network so everybody knows.

Thanks for having me out. It's a lot of fun.

MR. McKALIP. We really appreciate it, James. Any questions from our panelists? Ritu?

MS. NALUBOLA: I have one quick question. I think you mentioned that what you're looking for, as you phrased it, good information. Can you give more

specifically what areas, what types of information? I mean, I think that's what we were getting at with the first question.

MR. ALLISON: The good information that I look for is stuff that – boy, this is really hard to put in a term that's not guttural at times. I want it clean. I want it unadulterated. I need it scientific and unemotional. The information right now that you get on CRISPR comes out so fast, you really have to double, triple, quadruple check your sources. If it's coming in off of anything on the 'net that I don't like, I can't trust it. But if I look deep enough or if I know who to talk to, to get that information and those communication networks are set up, it's a home run. I can't – I'm taking care of our future when I'm teaching these kids, so I've got to know who to go to, to get that information. Good, bad, I just got to know who to trust.

And so working with industry like I have, I've started to put this network together. Like I say, we just kind of create these conduits and everything else to make the connections go. With help from you

guys, the networks can just be really stable, and that's the big thing. I don't want to have to throw it out and reinvent it every other year.

MR. McKALIP: Thank you, Jamie. We really appreciate it very much.

MR. ALLISON: Thank you.

MR. McKALIP: Next up, Yvette d'Entremont, according to my list from ScienceBabe.com, Vallejo, California. Yvette, are you in the room this morning? [No response]

MR. McKALIP: Okay, we'll move down the list and we'll check to see if Yvette is with us a little later.

Wendy Hershey with FEP of Concord, California.

[Inaudible comment]

MR. McKALIP: Do you want to come to the microphone? You can just make those remarks.

[Inaudible comment]

MR. McKALIP: Okay. Thank you. So we'll make sure the record reflects that Ms. Hershey did not intend to provide prepared remarks in her

registration, that she had checked the wrong box, and she did express general mistrust of the agency information that she has received to date. Is that a fair characterization?

[Inaudible]

MR. McKALIP: Okay. Thank you, Wendy. Appreciate that. Next on my list, Dan Jansen who is with Curriculum for Agricultural Education from Christmas Valley, Oregon. Dan, if you would please come forward to the microphone.

[Inaudible comment.]

MR. McKALIP: My list had indicated that Clay was not present, so if I'm incorrect on that, I will be updated.

MR. JANSEN: I don't want to steal somebody's spot. Thank you for having this meeting. My name is Dan Jansen. I work as the Project Director for Curriculum for Agricultural Science Education, or CASE as it's known. We work primarily in a little different space than what your questions, when I read them, they kind of addressed more the broad consumer. And just like the previous speaker that was from the high

school in Ohio, my space is middle school through post-secondary education, formal education.

What we do, we're not a company; we're actually just a project of the National Council for Agriculture Education where we're developing curriculum and teaching resources for teachers to use as well as the professional development for them to use those materials correctly.

I wanted to address two courses that we've worked on, one of which is the animal and plant biotechnology course, a year-long course for our juniors and seniors in our high schools. We also have a food science and safety course as well, which General Mills and Cargill help to support that particular course.

We have about ten courses overall in our sequence of courses that we're trying to develop, agriculture literacy and consumer choices when it comes to agricultural products. Those two courses that I mentioned, the food science and safety course, as well as the animal and plant biotechnology courses, are two of our most underutilized courses in the

country. We're in about 41 different states right now that use our curriculum in some form or some level.

So I just wanted to address some of the barriers that we're having in terms of getting teachers on board to use a course like biotechnology, which we see as so valuable as we talk about communication, and we're touching a part of our population that's the most influential as they grow up and get up to the consumer, and information stages of their lives and careers.

A lot of our teachers in agriculture, now I work in the world of Ag teachers, they're very hesitant to go down the road of biotech because of the science-intensive nature of the course. So we try to work with them and coordinate with their science teachers on delivering this course, but we're still kind of stuck back in the 1950s to some degree. Our southeastern states or southwestern states, or really the whole west if you will, very traditional agriculture, very production-oriented focus, which as we know, as those of us that are farmers in the room, know that's a very small segment of our population. I

have folks like bare crop science Dow, DuPont Pioneer, as well as General Mills, coming to us and saying, we need more quality graduates to come and fill these positions or to come and help talk about GMOs to the public in some way, and we can't get those students into the pipeline.

So in Ag education, the problem is trying to get our teachers to change, and Lord knows that's going to be a challenge for a while. But our probably 40 to maybe close to 50% of our teachers are very progressive, very cutting edge, and so we are working with those teachers on how to implement biotechnology at the high school level to get those kids going into that focus.

But their challenge is in, and I use a teacher from Maryland as my example. He actually spends 50% of his supply budget on the consumables, just the consumables to operate our biotechnology course in his high school, that only serves about 14 to 16 students annually out of the 200 that he sees. So it's a major hit when you start putting those numbers to a student output in that program. It's very

challenging for him. And so we've worked with companies like Bio-Rad who's here in the room, Vermeer, DuPont Pioneer, wonderful. They're providing $5,000 grants to teachers for supplies and equipment. But that's not a sustainable approach, so we're trying to figure out ways that we can encourage teachers to get that startup, autoclaves and centrifuges, and pipettes are just expensive equipment to model real-life practice of biotechnology to help those students to understand and project what biotechnology is.

You talk about trying to communicate what biotechnology is. If you've done it, whether you're in that career or not, you have a greater appreciation for what that profession is about or what that aspect is about.

So that's some of our challenges that we're faced with, and I just wanted to bring that up. Money and time is always the big issues as we try to educate public, but we have an opportunity with CASE, and I just – sometimes these discussions go down the road of, well, we need to develop curriculum resources. We've got tremendous curriculum resources and

professional development for teachers. We need to find a way to help support their efforts in bringing it alive in their classrooms because that will have a direct impact.

I want to take that hat off for a minute. I also have an alfalfa farm in eastern Oregon where we export thousands of tons of alfalfa hay to Pacific Rim countries. My concern is in the last three years I've eliminated all of my Roundup Ready GMO crops, and I've done so primarily from a marketing standpoint. We'll have folks come in from China or Japan to tour the farm, and once they learn that we have that crop on our property, they don't want to even entertain any more discussions about our particular farm.

That got me thinking about the perception of when those foreign markets are not even able to recognize or entertain a GMO crop, the perception that is then conveyed back to the U.S. population. I think that's another area, and I know we can't change foreign politics and we can't change that direction, but I think it's important that we try to figure out ways to curb some of that negativity that we hear from

our foreign marketplaces, because it does impact us, our farming.

So thank you very much, and I appreciate it.

MR. McKALIP: Thank you, Dan. Any questions from the panelists? Okay. Thank you. Next up, John Cawley representing Pacific Gourmet from Brisbane, California. John.

MR. CAWLEY: Thank you. My name is John Cawley, and I have a small food service distribution company in the Bay Area. I think I can say with reasonable certainty that I will be the least qualified person to address this panel today. I have absolutely no science background, and I've spent most of my life working, cooking, and selling food to restaurants, so I do appreciate your indulgence, and if I roam off-topic, forgive me.

I asked to speak today to express my concerns and fears about the timetables for and the pressures on the FDA regarding the approval of genetically engineered crops and their attendant maintenance, that refers of the impacts on farm workers, pollinators, and ultimately the consumers.

It should trouble all of us that the word regulation has become anathema in some very influential circles. The mission of the FDA we know is to protect the public from potentially dangerous food, drugs, and cosmetics. That mission is put to the test every day as powerful economic and political interests pressure the agency to fast track or soften objections to various products or processes.

However, what the public too often hears is that Chicken Little Luddites and knee-jerk environmentalists are pressuring the agency to jam the wheels of progress by handcuffing industry with useless and time-wasting regulation. In reality, with so much innovation occurring, and the great economic rewards that come to market first, businesses are too often impelled to bulldoze through approval without fully considering the long-term safety for the public or the planet. One could fairly argue for much tighter regulation. I would cite the overexposure to antibiotics in the food chain and the increase in resistant bacteria as an example.

When we think of genetically engineered

organisms and their [unintelligible] impact, they need to be considered both individually as a system and as a unit. This is an onerous job for already highly tasked agencies with limited budgets that are fully dependent on Congressional whim. What I suggest today is that government plan and institute the Office of Unforeseen and Unintended Consequences, might be more appropriately called Department of What Could Possibly Go Wrong. Its duty would be to monitor and inform the responsible branches of government of the likely potential of a policy or action going terribly awry. It should be comprised of a Noah's Ark of experts from academia, science, industry, farming, ethics, military, etc. Its purpose besides advising the relevant branches and bureaus of government needs to be to inform and educate the citizenry, when appropriate so they may be allowed to play their role in democratic process.

Every agency of government would benefit by having a corresponding entity of related experts that would report on any inherent risks it foresees. Imagine what harm could have been or might be

prevented if a truly functional body like this existed. Wars in Iraq and Afghanistan may have been avoided. DDT could have been abandoned years earlier, and Agent Orange would never have been sprayed indiscriminately on populated areas and our own troops.

The potential for a runaway train event with GMOs is real and must be the top of every decision the FDA and EPA makes. We've already seen such events as the recent destruction of 3.6 million acres of non-GMO soybeans due to the drift of Monsanto's dicamba, an herbicide developed to kill the Roundup Ready resistant super weeds that are now the unintended legacy of GMO food crops and animal feed. The carcinogenic properties of these glyphosate agents is an ongoing topic of concern.

The innovation and discoveries of our era are breathtaking and remarkable. We see and reap the benefits every day. A problem, however, lies with industry rushing to monetize their or others' research, think of the NIH and universities, with minimum or due diligence as to the long impact.

Call it the nature of business or management's responsibility to the shareholder, or call it plain greed, but this impulse must be vigilantly restrained.

J. Robert Oppenheimer spoke to this, saying scientists are not delinquents. Our work has changed the conditions in which men live, but the use made of these changes is the problem of governments, not scientists. This is a problem for the FDA, the EPA, and the USDA. Oppenheimer feared he enabled the destruction of mankind by helping create atomic weapons. Releasing the genetic genie may be even more dangerous to the species. I wish the EPA, the USDA, and the FDA great wisdom. Thank you.

MR. McKALIP: Thank you, John. You may be one of the few retail consumer interfacing panel members that we have. I'm kind of interested to know from your perspective in the retail locations that you deal with or location, how do consumers who come in get information? Are there shelf talkers near a product? Do you have other types of information located at the point of sale that a consumer would see or interface

with?

MR. CAWLEY: Well, actually, I can't help you there because I do food service through restaurants. And in the Bay Area, as you're probably aware, there is a stronger concern perhaps than in other parts of the country about the makeup of the food that people eat. We see a premium for non-GMO product and for organics as well. However, that premium stops when the price gets too, too high. So there is a little perhaps hypocrisy there. But it's still in demand, and I think it's a growing area, and we've seen it with the Walmarts and the Costcos bringing on more and more organic product, for example.

MR. McKALIP: Thank you, John. Any other questions from the panelists? Okay. Appreciate it very much. Next up, Christine Trane from Pacifica, California. Christine, are you here in the room? Okay, we'll come back to Christine. Karl Haro von Mogel with Biology Fortified, Inc. out of Stockton, California. Karl.

MR. HARO VON MOGEL: Good morning, everybody. My name is Karl Haro von Mogel and I'm with Biology

Fortified. We're an independent nonprofit organization supported by members of the public. Our mission is to enhance public discussion of biotechnology and other issues in food and agriculture and we're really pleased to see Congress supporting an Education and Outreach Initiative on biotechnology through the FDA and we're happy to help inform this process from our experiences.

I'd like to address the three questions that are posed here this morning. For the first question about where do people get their information, in general, consumers don't tend to be very well-informed about where biotechnology is used in food and agriculture and the science on it, and also the regulatory scrutiny that the technology receives. The FDA can play a pivotal role in helping the U.S. public understand these aspects of the technology.

The most useful information for consumers would be general information about the technology itself, how it works, and the regulatory process. The FDA can work with the EPA and the USDA to share information about the entire Coordinated Framework

from the perspective of the technology and the regulatory process, but not really focusing on the specific products.

The FDA has a critical role in safeguarding the health of the public, and in that role the FDA can clarify any nutritional claims made by developers, including making nutritional equivalents of biotechnology-derived foods clear to the public.

The role of the FDA should not be to focus on specific products where there's no substantial difference between them and foods produced through biotechnology, but to clarify how the FDA determines this aspect of foods during the regulatory process.

However, the FDA should provide specific product information about those products with altered nutritional properties, some of which are just beginning to come out. So, so far we have a lot of foods that are not nutritionally different but we're starting to see that change. And so the public needs a good place, independent of the companies themselves, to get information about these and find out how they may affect them nutritionally, both positively and

negatively.

The safety of products produced through the use of biotechnology is also a critically important issue for the public. A 2016 Pew Research survey on the public and scientists' perspectives on biotech showed a 51-point gap between the public and the scientific community on the issue of safety. There is a scientific consensus on the safety of genetically engineered crops currently on the market, yet the survey indicated that the public perceived greater disagreement among scientists than there actually was. The survey also indicated a low level awareness of the issue and knowledge of the subject.

We've observed similar trends in our experience and have devoted significant efforts to communicating the safety of these foods, but by making the FDA's role in determining the safety of the products of biotech more familiar to the public, the FDA can help increase public awareness.

Information that would not be useful would be specific rebuttals to every claim made. There is so much misinformation that debunking can quickly become

a waste of resources and can have a backfire effect by elevating those claims.

That said, common misconceptions might be clarified in, say, a Q&A style or other documentation that's secondary to the primary information sources. People are increasingly interested in learning about farm impacts and working with the USDA you can provide general information about the farming context in which these crops are grown.

So to address the second question about where do consumers most often receive the information on this subject, I mentioned the Pew poll, and that shows that there's a lot of work to be done. Understanding of biotechnology is lower than other subjects including evolution. If you just simply do a web search and put, are GMOs blank, add a letter, go down through the alphabet, you will see that the safety question is one that comes up very, very commonly in every kind of suggested search result. That's something that people are very interested in learning about. But if you start conducting those searches, you'll see that the first pages that come up

usually end up being pages from organizations and individuals who are 100% opposed to the technology, or the companies themselves who I think would be pretty much 100% in favor of it. So some sources in favor and some sources against are funded by competing industries or even NGOs where their business model is based on alarming the public.

But consider the different media types. There's traditional media sources and there are social media sources. There's very little mainstream media coverage. It's only when it gets up into some controversy related to a study that came out or a few other things like the National Academy of Science's reports that come out where the traditional media covers it. But it usually doesn't get very much attention, and usually that kind of coverage is sensational.

Yet the research shows that the vast majority of the American public is not polarized about the issue. You'll certainly hear this morning, or already some very differing views on biotechnology, but the vast majority of people are still open-minded

and are still curious and looking for information, and they need a good place to get it from.

So to address your third question about how to best reach consumers with science-based educational information, that's something we've been trying to think about a lot. So the FDA recently put out a small infographic on how biotechnology and plant breeding works. It was very, you know, a little beads on a string, and it was very helpful and the associated text was very informative for the public, and it was actually communicated very widely, and we were kind of surprised. It just came out. It was very informative and useful. We'd like to see more resources of that kind, concise and shareable for social media.

We'd like to see resources that professionals, including doctors and dietitians, can point to when members of the public have questions about biotechnology. These need to be social-media-friendly and can include images, maybe even short videos, perhaps fact sheets, that doctors and dietitians can hand out or put on a bulletin board, lessons for public school teachers to use.

You can share information from well-respected sources such as the National Academy of Sciences reports on biotechnology would be a very good source for comprehensive information to base it off of.

We'd also like to see the FDA work with science communicators that have been working in this space. You don't need to reinvent the wheel. Work with those who have real world experience and know the landscape. Then also consider the deficit model of communication versus other models. So the deficit model is if you have this gap of understanding, it's just, oh, we'll put out facts and therefore people will learn this and then you've closed this gap, this information deficit, as it's called in science communication. But it turns out that's not how everybody thinks. It's not how everybody works. We think about trust, we think about values, things that intersect it, and those color our interpretations of those facts. So perhaps thinking about a trust model of communication would be very helpful.

The information is out there if people want

to find it, but instead they're finding information from people that they trust. So federal scientists are already fairly well trusted, but they aren't necessarily within reach of the average consumer. Getting both the FDA and other scientists and science communicators in front of wider audiences, both virtually, in the media, and in person, can make a huge difference in gaining trust. Getting scientists, farmers and other good communicators in all sorts of radio, TV, and social media shows would reach many people.

We also lastly suggest creating resources like slide decks, making those available for science communicators to use, not on behalf of the FDA, but in general to help people provide fact-based information in their communities. You could even send speakers to conferences for professionals such as the Academy of Nutrition and Dietetics conferences, general science conferences, and many others to ensure that professionals can easily find resources. Thank you.

MR. McKALIP: Thank you, Karl. One thing really struck me in your comments. You mentioned using

social media, that there's a role there that we should try to utilize. Then I heard you talk about the trust model versus the deficit model. When I think trust model, I think in social media there's so much information out there, so how specifically would you recommend that these three agencies, through an education and outreach initiative, might somehow utilize social media in that area?

MR. HARO VON MOGEL: Just from the top of my head here, providing things that could be easily shareable, and then finding networks, many of which already exist -- I'd be happy to provide more information about this -- and put it in a form that they can all start sharing. Sometimes we get surprised when we put together a meme, just a little bit of information about something that we just learned and think people should know, attach an image to it. We send it out there and sometimes they'll just go everywhere, and it surprises us.

But some of them like that beads on a string graphic that came out did actually go pretty far, and we've made some infographics ourselves, and some of

them – I end up showing up in Facebook discussion intending to go, oh, we made a graphic that explains this, and somebody's already put it in there. So at least creating those kinds of things and finding who you could give them to would be helpful. And even you've got different kinds of networks who you could tap into. I mentioned dietitians for one thing. There are actually a lot of dietitians on social media, and I'm starting to see more and more of them. My wife is also a dietitian. She just went to the FNCE Conference and saw all kinds of stuff going on there.

You can frame these around the issues that concern them and their clients, and get this in some of their hands and see if they are willing to share it and with a little link in it, they can go to the FDA site maybe to find out a little bit more about it, I think would do a lot. But it's hard to know sometimes what will get passed around. So there's a lot of experimentation involved just like in science.

MR. McKALIP: All right. Thank you, Karl. Any other questions from our panelists?

MS. NALUBOLA: Yeah, I have one quick follow-

up along the same lines. You mentioned no need to reinvent the wheel, work with those with real world experience or science communication. I think it would be helpful for us to know in your comments that you submit to the docket or give us specific concrete examples of such entities that you think we should –

MR. HARO VON MOGEL: Sure. And we're going to be polishing up our comments and submitting them in written form. Be happy to provide more information and any communication afterwards. There are a lot of science communicators out there, and the landscape is changing. I even just went to a plant breeding conference in Davis a couple of months ago, and the students there, all the grad students wanted to do science communication. So some of them are just, they know the impact, positive or negative, of the field that they're working in and they want to actually get involved but to get some support from – to help them pursue those interests while they're studying and all that would be great.

MR. McKALIP: Thank you, Karl. Those are good suggestions. Some of those techniques are things that

probably our agencies just aren't using too much currently, but I know how those memes work. I have a 12- and a 14-year-old and next thing you know there's a picture of me and they send it and suddenly everybody's got it, and I'm getting funny emails back from them, so I know that those things get circulated.

It is time for a break, based upon our agenda. So if we could be back in the room promptly at 10:25 to continue. So again, there are facilities on this floor, food located one escalator ride above us. So please be back in the room promptly. We're going to start right at 10:25. If you haven't signed up to speak and would like to, see Juanita wearing the green coat with the blue ribbon on her badge. Rightfully she has that blue ribbon on there for good reason. Okay. Thanks a lot. We'll be back at 10:25.

[Break]

MR. McKALIP: Okay. Why don't we go ahead and get started? Our next speaker on our list is Dana Perls with Friends of the Earth from Berkeley, California. Dana.

MS. PERLS: My name is Dana Perls. I'm a

senior campaigner with Friends of the Earth, U.S. I'm pleased to comment on behalf of Friends of the Earth to the FDA, USDA and EPA about the new Agricultural Biotechnology Education and Outreach Initiative. Some of this also may actually be applicable to the Coordinated Framework which you mentioned earlier.

The stated goals as we understand of this program are to provide education and outreach to the public on agricultural biotechnology and food and animal feed ingredients derived from biotechnology. In my comments I would like to share suggestions about what Friends of the Earth believes should be done in order to have an effective initiative which will build credibility and trust. In particular I will focus on food and animal ingredients derived from what I will call genetic engineering including gene editing and synthetic biology.

So your first question was what are some specific topics, questions, or other information that consumers would find useful? I'd say that the first one is that people want to know both the potential benefits and more significant the potential risks

about agricultural biotechnology and biotechnology-derived food products and animal feed. As stated, the initiative does not explicitly say it will educate people about the known and unknown risks, and this omission is alarming.

The imbalance which we've experienced with information about first generation GMOs, the industry PR, and the reports which have shown industry influence on government regulations and assessment has in fact created distrust amongst the public. So credibility requires you to address the concerns and name clearly what actually we don't know, what hasn't been studied, what still needs to be understood. Credibility means that this is not to be biotech industry driven education. This also means staying away from false generalizations like there is scientific consensus about safety. These generalizations erode credibility.

People want to know what modern genetic engineering is. What is synthetic biology? It must be clear that whether it's RNAi, TALEN, zinc fingers or CRISPR, this is genetic engineering.

It also should be clear that we are still learning about these techniques. There's a lot of PR about CRISPR, particularly in hopes for its application, that it's precise, that there are no problems. And one would think from the way the media poses, that all the problems have been worked out. We know that this is far from the truth, and the FDA needs to educate people about the very real concerns and the questions that are also being discussed in scientific journals.

People want to know what the different genetic engineering applications are. This has changed vastly in the past ten years. We are no longer just talking about GE cotton, soy and corn, but now we are also talking about GMO apples, and bio vanilla, and BioDirect RNAi spray, GE salmon, GE moths, GE algae oil, omega-3s. The list has expanded far and beyond what most people know.

People want to know how these new biotech applications are going to be assessed and regulated. I think there are a number of questions that must be addressed. And if the answers aren't known, then they

need to be honest about it. What are the regulatory gaps that still need to be addressed? Although the FDA may have some existing risk-assessment frameworks, I would argue that there are no currently no adequate national regulations which fully address new genetic engineering techniques and gene editing techniques such as CRISPR. Particularly some of those which are already being applied today and whose products are already on the market.

People want to know what the new processes will be for assessing and regulating these biotechnologies. We desperately need updated processes because there is a higher uncertainty of risks posed by the new genetic engineering and gene editing techniques due to syn bio’s increased depth of intervention in living organisms and biological systems.

The rapid rate at which these technologies of synthetic biology and genetic engineering are evolving pose new challenges for regulators, and this needs to be transparently acknowledged in any communication.

Friends of the Earth recommends the FDA, the USDA and the EPA use a precautionary regulatory approach, one that is process-oriented as opposed to product-oriented, and in which the FDA assesses and addresses the direct and indirect impacts and risks throughout the entire life cycle of genetic engineering production from the inputs to the labs to the final product. Risks may include environmental contamination, worker exposure, as well as socio and economic impacts.

It should also be clearly noted and addressed in education that current generally regarded as safe is a voluntary safety assessment, not a mandatory third-party assessment. And when companies say this has been considered GRAS, there is a lot of misunderstanding about what that means. So the FDA should be transparent with consumers. It should be made clear that no new kinds of genetic engineering should be by definition GRAS. They simply have not been researched long enough to be considered general, and there hasn’t been enough safety assessments to be considered safe.

And most people don't know but should that companies often present their own data analysis to regulators and may put their products on the market without FDA assessment. We saw this recently when the FDA said that it couldn't deem the Impossible Burger's synthetic biology heme as safe based on the existing data. There just simply wasn't enough data to be able to make that claim. However, Impossible Foods then put the Impossible Burger on the market anyways without having shared new data with the FDA, to demonstrate that the initial concerns had been resolved.

The FDA should use its authority to pull adulterated foods like Impossible Burger off the market when they are going ahead of assessments and regulation.

Again, ingredients derived from genetic engineering, particularly synthetic biology and gene editing, should not be assumed to be GRAS. It sets an untrustworthy precedent if companies are allowed to slip new genetically engineered ingredients, food additives, and animal feed ingredients onto the market merely claiming that it falls under GRAS. People need

to know that safe is different from not yet knowing the hazards. And the FDA and USDA will need to address how they will create robust and mandatory assessments and regulations.

Lastly on this question, the FDA and USDA must address GMO labelling. Polls show that 89% of people want their food labelled, and this should be clear via on-package labelling, not QR codes which are not accessible to the majority of people. Labelling should apply to all ingredients derived from genetic engineering including genetically engineered processing aids, gene editing, and synthetic biology.

So on the question of how and from where do consumers receive information, unfortunately we don't have ample insight as to how consumers receive their information on this topic. We keep up-to-date information on our website and our members receive timely information through email, social media, our website as well as direct mailings.

The question about how can the FDA in coordination with the USDA best reach consumers with science-based education, also we don't have strong

recommendations as to how to distribute information aside from the way my organization does. However, it will be important for the FDA to not reinforce big agriculture PR claims that we now know that data doesn't support. So I'll just leave you with saying that the FDA really needs to claim a space of full transparency using science-based information about the potential risks as well as the benefit, and talk about how the agencies will address the need for mandatory regulations and assessments for these new applications before they hit the market.

Thank you for this opportunity to comment.

MR. McKALIP: Thank you, Dana. Any clarifying questions from members of our panel? Thank you so much, Dana. Really appreciate it. Next up we have Lisa Germo-Almendarez with the Empowered People of Menifee located in Sun City, California. Lisa.

MS. GERMO: My name is actually Lisa Germo. It was spelled a little – everybody gets it wrong. I'm here representing Moms Across America. We are a coalition of unstoppable moms raising awareness and GMOs and related pesticide in our food systems.

Empowered kids, healthy moms.

I am not a scientist. I'm here as an awesome mom, and through my research forced by having a sick child, I am here five years later. I believe that we really need to look at the independent science, not science from any chemical company including Monsanto.

Did you know, well we all should know, that 80% of GMOs are engineered to withstand glyphosate - based herbicides or Roundup? If there is going to be any public education about GMOs, it should include the truth, the risk of glyphosate herbicides.

Glyphosate has cancer-causing effects. LARC branch of WHO declared glyphosate a probable carcinogen. The California EPA OEHHA placed glyphosate on Prop 65 July 2017. There are thousands of lawsuits pending against Monsanto, the manufacturer of glyphosate, for causing non-Hodgkin's lymphoma. These lawsuits have also exposed cover-up, collusion with the EPA to hide harm and risk from the public.

Roundup is a proven endocrine disruptor causing birth defects, infertility, development delays and more. Patented as an antibiotic, absorbed through

contact, can and will destroy beneficial bacteria in our bodies and weaken our immune systems, disrupts hormones, causing depression, mental illness and others.

A recent study proved to cause non-alcohol liver disease. According to the Liver Foundation, one of ten Americans now have liver disease. Proven to be a neurotoxin, a 20-plus year study showed children who live near areas where pesticides were used have lowered IQs. Neurotoxin damage contributes to dementia, Alzheimer's and autism.

What is the cure cost to our society from the harm caused by glyphosate and GMOs? Glyphosate has shown to stimulate growth of breast cancer cells in one part per trillion. One part per trillion is equivalent to 22 Olympic-sized pools. The EPA allows up to 30 parts per million of glyphosate residue on our nonorganic and GMO food supply. This is the information that the public has the right to know.

The FDA created a loophole in the safety testing by deeming GMOs and related pesticides a process and not also an additive, even though testing

can show GMOs and pesticides in our food. The FDA knows that if deemed GMOs and a pesticide, also an additive, then manufacturers would have to test for safety, labelling on GMOs and pesticides in our food.

The FDA deliberately supported food manufacturers in hiding the fact that GMOs and pesticides in our food by deeming them only a process and not also an additive. This is not protecting the public. This is protecting the profits of Big Ag.

Once again, 80% of the corn are engineered to withstand this glyphosate. Glyphosate is not safe, although the manufacturers and the EPA claim that glyphosate herbicides are safe. The fact is, that the policy of the EPA is not only to require safety testing on one ingredient of the pesticide and not the full formulation. So the products that are used in our food are not shown to be safe, and any amount to say that these pesticides along with GMOs are safe is scientifically unfounded. The fact that the other ingredients in the formulation have been proven to be a thousand times more toxic than glyphosate alone. It is not true that glyphosate is the same as

conventional foods. No studies have shown that. We know that it is lower in nutrients. Why would we spend millions of dollars protecting the profits of Monsanto and their lies?

I am a parent of a sick child, and it's taken me a long time to do a lot of research, and it's been very difficult because it's hard to find the truth out there. I think that us out here looking at each one of you individually and going to your websites, I feel that I should be able to trust you and the information that's on your pages, and that is very difficult for somebody who is a stay home mom with some college education. I've really had to do a lot of research. After my research, I still didn't know what was going on because there was always two sides of the story. But what I do know is that if there's a poison in my food, I do not want that on my dinner table at all. If there is two sides to the things, I'm going to choose the side without the poison. Thank you.

MR. McKALIP: Thank you very much, Lisa. Members of the panel, any clarifying questions? Okay,

next up, Stephan Herrera with Evolva Incorporated from Larkspur, California.

MR. HERRERA: Hello, and thanks for giving me the opportunity to express some points to the panel.

My name is Stephan Herrera. I am Vice President of Strategy and Public Affairs for Evolva, as you say, and my background is that for 20 years I was a reporter covering the business, science and politics of biotechnology, and after I changed careers I went into the industry that I wrote about.

I want to first articulate what we are and what we do. We produce health, wellness, and nutrition ingredients using biotechnology in fermentation. So ingredients that industry would previously source from, shall we say, plants and animals or petro chemicals. Those same ingredients can be produced by fermentation. So we don't go out and produce commodity chemicals. We're typically going after a very select group of ingredients.

We believe strongly that corporations need to work very hard at proving to the public that they are trustworthy and deserving of trust, and that one

way that you can do that, not the only way, is to be transparent. So the point I'd like to make in context of the forum here is that transparency, whether it's by a label or a website, requires a very active effort. It's not passive. So simply putting information up on a website or putting a label on a food product is not active. That's passive. And it completely, I would say, leaves a lot of value on the table where consumer information and education are concerned.

We do not, as a matter of policy, believe that you simply need to go out and educate the people and they will therefore, once they're informed, they will side with industry. But we do believe that you need to provide information and let the public make up their own mind. Very difficult for the public to be able to do that if there's simply a label with an acronym on it. So I would argue that putting a label on a product is not the endpoint. Informing and educating the consumer is the endpoint. And the only way that you're going to be able to do that properly is if there's context about what does that label

really stand for? Is it there to inform that there's an ingredient that was either processed or is a genetically engineered ingredient in the finished product? And if so, then what does that even mean?

And I think the public also needs to understand sort of the broader picture, which is the fact that there is a scientific consensus, most recently articulated from the National Academies of Science last year, that found that ingredients produced from biotechnology, when you compare the U.S. to Europe, Europe has been non-GMO, U.S. has been GMO by and large, there is no difference. There is no safety impact.

So if the public is to understand what that label is for, then they need to understand first of all that there is not a safety issue. So if it's not a safety issue, then why is the label there? And I think that we're not doing a service as an industry, as a government, if we're not really looking at the big picture into not just looking at how to put something on a product that indicates that it has gone through some process, but what does that mean? What does that

mean for your health? What does it mean for the process that product went through? It needs to be a big picture.

So I would say that one of the recommendations I have is responding to where do people get their information. Well, study after study shows that the vast majority of the public gets their information from social media. So I would say that the three agencies that are here today would do well to really understand concepts like search engine optimization, number one, and number two, they need to understand how does the information that appears on the first page of a webpage search get there. It's not always the most factual, the most calm, the most balanced information that shows up on the first page. In fact, it's often just the opposite. Not always, but often.

So how do we get to concrete recommendations? I would say the theme of my recommendation overall is mind the gap, and that is the gap between what the government does and tries to articulate versus what the public does to gain

information and try to understand what that information means.

So one thing is possibly to create a perception reality document that goes on your website, that's managed by somebody actively. It's updated, it's put out on social media. Hey, this is the newest perception versus reality point of the day on food facts. I think there's a massive gap between perception and reality of safety about how ingredients are produced today. Not just from genetic engineering ingredients, but how much do people really even know about GMOs? How much do they know about organic food? The answer is very little, very little. I think the people in the room here are not representative of the consuming public in general. We live this. We have to learn it. Most people don't have to, so they don't.

The second point is that I think that there should be working with your three agencies, working with science educators, is if you could put together food science and politics public education campaign, and really work with professional communicators on how to inform and educate on those, the difference between

food politics and food science, and then get out there and inform. Again, transparency is active. So partner with TED. Partner with the Aspen Ideas Festival. Partner with Neil deGrasse Tyson. Figure out a way to get that information out into the public where there is at least a chance that it can start to filter into the consuming public.

The final idea is I live in Utah, and this is a very conservative state. The officials there were very concerned about teenagers and vaping, because of this misperception that vaping is somehow safer than cigarettes. They spent a lot of money on public education campaigns and it did exactly nothing. And then somebody finally had the idea, hey, wait a minute. Why not go ask the teenagers themselves to produce a video that informs and educates about this?

And so I suggest based on this, it's an N of one, but I suspect that if you spent ten minutes on the internet, you could find lots of evidence supporting the fact that there are many other ways to communicate and sometimes adults who are in government positions, industry positions, are the worst

communicators in terms of trying to educate the rest of the public. So maybe hold a challenge where it's funded, you have high school students who are competing to produce a video on food facts. And you could have a rotating series of food facts videos. It could be a two- to three-minute video, and that's just one of the out-of-the-box ideas, again, to try to figure out how to bridge the gap between the consuming public who needs to know more about this information, deserves to, and must, versus those of us who talk about it, who make those ingredients and products. Thank you very much.

MR. McKALIP: Thank you, Stephan. Any questions from members of the panel? Appreciate it very much. Thank you. For those of you following the list, Zen Honeycutt won't be with us here this morning, so we're going to go to Rebecca Spector with the Center for Food Safety located right here in San Francisco, California. Rebecca.

MS. SPECTOR: Good morning, and thank you, members of the agency. My name is Rebecca Spector and I'm the West Coast Director with the Center for Food

Safety here in San Francisco.

CFS is a national nonprofit organization working to protect human health and the environment from the impacts of potentially harmful food production technologies.

CFS scientists have been studying genetically engineered crops and foods for more than 20 years, and I've been professionally working on the issue representing the interests of farmers, fishers, and consumers for 20 years. This is an issue that is of great concern to our membership of nearly one million people.

We appreciate that the U.S. Food and Drug Administration and the U.S. Department of Agriculture acknowledge that the public has the right to accurate information about how their food is produced, including if it is produced using genetic engineering.

The USDA is currently developing regulations for labelling of GMO foods, and our position is that the agency should mandate on-package labelling of foods that contain GMOs, as this is the only way to ensure equal access to that information.

In regards to providing the public with more information about GMOs, CFS' position is that the government agencies responsible for disseminating information about GMOs should, one, not present information that is false and misleading; two, not present information that is speculative and unproven; three, not rely solely on information provided by the corporations that are producing and profiting from GMOs; and four, provide information that is proven to be true and not contradicted by federal agency data or reports.

The biotechnology and chemical industry touts claims about GMOs that are speculative and at times false. These claims should not be included in educational materials about GMOs that are disseminated to the public. For example, GMOs do not reduce pesticide use. According to a study by Dr. Charles Benbrook, 404 million more pounds of pesticides were used in the U.S. in the 16 years from 1996 to 2011 due to the introduction and widespread adoption of GE crops.

His analysis is based on gold standard data

from USDA's agricultural chemical use program. Recent pesticide use estimates from the U.S. Environmental Protection Agency support this USDA-based assessment. Over the course of seven years from 2005 to 2012, annual agricultural herbicide use in the U.S. rose by 34% from 420 million pounds to 563 million pounds. And for those in the audience who may not be as familiar with the technology, the reason for these pesticide increases is because more than 80% of the genetically engineered crops are designed for one purpose and that is to be resistant to the spraying of herbicides such as glyphosate which is the active ingredient in Roundup, so that farmers can spray herbicides to kill weeds without killing the crops.

As such, the false claim that GE crops reduce overall pesticide use should not be presented to the public. We encourage FDA and USDA to instead truthfully inform consumers that the major effect of GE crops has been to increase the use of weed-killing pesticides, because many consumers want to consume foods that reduce pesticides in order to reduce negative impact on human health, wildlife and water.

In addition, currently commercialized GMO crops do not increase nutrition. Despite abundant industry hype regarding genetic engineering experiments, in which crops are modified for improved nutritional purposes, there are currently no commercialized GMO crops that increase vitamin or mineral content. For example, decades of effort have failed to produce a commercial GE rice variety with enhanced *beta*-carotene content, commonly referred to as Vitamin A rice. As such, the false claim that GMO crops increase nutrition should not be presented to the public. Those crops do not exist.

Currently commercialized GMO crops have made no special contribution toward feeding the world. The chief cause of world hunger is poverty and a lack of adequate distribution of food. To the limited extent that new crop varieties would increase yield potential can help, genetic engineering has not been a positive contributor. There are currently no GMO crops approved or commercialized that are engineered for higher crop yields. A 2016 report by the National Academies of Sciences found a steady increase in crop yields that

spanned both the pre-biotech and biotech eras, strongly suggesting that non-GE factors such as advances in conventional breeding methods have played a critical role in increasing crop productivity.

By contrast, they found no evidence that GE traits provide measurable increases in crop productivity. As such, the false claim that GMO crops have increased yield and are needed to feed the world should not be presented to the public.

Genetic engineering has proven to be inferior to conventional breeding in developing drought-tolerant crops; thus, GMOs should not be promoted as critical for adaptation to climate change. Only one GE variety of corn that is designated as drought-tolerant has been commercialized, but USDA concedes that it is no more drought-tolerant than some conventionally bred crops. In contrast, hundreds of conventionally bred drought-tolerant varieties of many crops have been developed and introduced into the market. As such, the false claim that GMO crops combat climate change should not be presented to the public.

In addition to the recommendations above,

the agencies should also provide the public with the following truthful information about GE foods. GE salmon, regardless of where they are raised, pose a clear and present danger to wild and native salmon populations. This statement has been presented in numerous scientific studies and was noted in comments to FDA from experts in transgenic fish, expert federal wildlife agencies, the National Marine Fishery Service, and the U.S. Fish and Wildlife Service, which recommended against the approval of this first-ever genetically engineered salmon due to the impact on wild salmon populations.

Recently approved genetically engineered crops resistant to the herbicide dicamba have resulted in massive injury to soybeans and other crops across the United States, and are negatively impacting farmers.

In one of the biggest stories in agriculture this year, the widespread adoption of Monsanto's genetically engineered dicamba-resistant soybeans and cotton have led to a massive increase in use of this highly volatile herbicide, resulting in unprecedented

levels of herbicide drift, injury to soybeans and other crops across the country. To date, there have been 2,708 official complaints from farmers about damage to their soybeans due to dicamba drift from neighboring farms and 3.6 million acres of soybeans have been injured across 25 states, though the true scope of this drift injury is likely to be much more.

The public deserves to know the truth about genetically engineered crops and foods. They should not be given information that is false and misleading such as the claim that GE crops reduce pesticide use, and should not be given information that is speculative and unproven such as the claim that GE crops would feed the world. Center for Food Safety would be happy to share our extensive research with the agencies tasked with providing information about GMOs to the public. Thank you for consideration of our comments.

MR. McKALIP: Thank you, Rebecca. Appreciate it, and appreciate your offer to share additional info with us as well. The drought tolerance, at one point in your remarks I think you said USDA concedes that

there wasn't a difference on drought tolerance. That'd be a piece that for sure I'd like to –

MS. SPECTOR: Sure.

MR. McKALIP: - offline with you get the sources for that and any of the background.

MS. SPECTOR: Definitely.

MR. McKALIP: Any questions from members of our panel for Rebecca? Okay. Thanks so much. Really appreciate your comments. Next up, Randy Krotz representing the U.S. Farmers and Ranchers Alliance from St. Louis, Missouri. Randy.

MR. KROTZ: Thank you and good morning, everyone. The approach to comments for this hearing, when I came to this, I thought a lot about addressing it, as many of the folks so far have addressed it. There's so much emotion around this topic that I thought it better to step back and give a little bit of an understanding of who we are and who we're funded by, in order to make sure that our approach to this is as transparent as we possibly can be.

U.S. Farmers and Ranchers Alliance is made up of 105 different agricultural organizations,

commodity groups, as well as corporations. We are largely funded by farmers and ranchers themselves. A vast majority of our funding comes from those organizations, but we do operate across the country. We represent farmers and on our board are farmers from Idaho to Maryland.

We work very hard to be production-practice neutral in our approach to agriculture and to our approach like conventional production of crops, using GMOs or not, or organic production. We truly do. We also, though, are generally pro-technology as an organization. There are so much technologies that is utilized on farms today that we do generally end up speaking to and through farmers' and ranchers' voices to millennials and oftentimes it's about technology because it is a way that we have found to connect very well with people.

Farmers and ranchers undoubtedly as we've heard this morning are one of the more trusted voices out there. We trust ourselves for information, all of us do. We trust our friends and neighbors. We trust our friends in social spaces. We also trust doctors

and dietitians and farmers and ranchers. And we as an organization have tried to take advantage of that to some degree, to move forward in advancing the conversations on technology on the farm, including GMOs by using the farmers' voice to do so.

I should have also said that our funding also, we also receive funding from Monsanto, Dow DuPont, Bayer, BASF, but again the vast majority and our governance comes from independent farmers and ranchers across the country.

I'm a farm boy from Kansas, and my father and brothers still farm today, and we do use GMOs on some of our property, and some of our property we don't. So I hope that overall as we try to engage the consumers in this discussion, as we try to get farmers and ranchers into discussions about GMOs, that we do it fairly, that we do it with people that have a knowledge of the technology, that use science first. We feel like that bringing science to this discussion is incredibly important. And overall want to do that on an ongoing basis.

We developed a process eight years ago

called The Food Dialogue which is truly having a panel, not unlike the one that's in front of me right now, with people from all sides of this discussion. We think it's important that all voices are heard. If they aren't all heard, then we won't be heard. And we all know that about ourselves. So we do try to do that on an ongoing basis.

We have a technology here that some would argue is science-based and safe, that you have Nobel laureates from across the globe that have declared it safe. You have health organizations from across the globe that have declared it safe. We as agriculture have done an inadequate job of engaging in the conversation to make sure that our position on the technology is understood.

It sometimes is hard to listen to all sides of this discussion, but we recognize it's incredibly important.

USFRA, U.S. Farmers and Ranchers Alliance, uses techniques like social media, public speaking engagement in all sorts of events. We produced the film Farmland which was truly just an effort to re-

engage the consuming community in agriculture, to get people thinking about farming and ranching again. I often tell the story that in the ‘60s largely across this country, consumers stopped going to the farm. Maybe eggs were the last thing that consumers came to the farm to purchase. There are certainly exceptions to that all over this country with small and local farms of course. But broadly speaking, that’s what occurred. And farmers and ranchers really failed to communicate with consumers for decades in a way that we should have, and to engage in a way that we should have. And that’s what USFRA is attempting to do.

We’re not funded to a degree to talk to all consumers. We’re not. What we try to do is go to super influencers. We try to go to consumer food connectors to work to engage them in this discussion on GMOs and other issues in agriculture and food production, to have them be notable and understanding and science-based around these topics. And again, those can be from dietitians to doctors to folks in the culinary industry, chefs are actually very trusted in this discussion, as are those in the wellness community. So

many of us today have trainers and people that we depend on that actually we maybe engage more regularly than we engage our doctors or maybe a dietitian or nutritionist.

So USFRA works to get information in front of those organizations to do that. We have looked at where consumers are on their acceptance of GMOs for eight years. We do trending research every year to take a look at what the understanding is. We know that consumers trust farmers and ranchers. Over 80% trust farmers and ranchers. The problem is, there's not a trust of how we grow and raise food, and that's what we're trying to change. We're trying to change it by making sure that consumers recognize that if you're after organic food, you should be able to get organic food. And you should know that it is. If that's not your choice, you should have the other choices as well.

On our farm, I know there's always discussion about pesticide reduction. On our farm we have virtually eliminated the use of insecticides on our farm because of GMOs. And one can talk about

claims around the environmental impact, the benefit of that I know personally if it was a path that my father went down because of the financial benefits to the technology, and also what he thought might be some environmental benefits to the technology.

We have a long way to go to help consumers understand how GMOs help us be more sustainable on the farm. We also owe it to consumers to make sure they know they have a choice, and that that choice can allow them to purchase whatever type of food they want to purchase.

With that I'll stop. Thank you very much.

MR. McKALIP: Thank you, Randy. Appreciate that. You used the term super influencers, and I heard you talking about doctors, nutritionists. I heard you mention chefs. I didn't hear you mention teachers.

MR. KROTZ: Actually, and thank you. We actually have a program called Discovering Farmland, which is a collaboration with Discovery Education which addresses, it's generally targeted at 9th through 12th at the high school level, and we're very proud of the program. It's relatively new. It's about

a year, year and a half old, and it literally addresses all production practices in agriculture. It addresses organic production, GMO production. It also addresses why we confine livestock, and other issues that are on the modern farm today. So we've had over a million students view it and 35,000 teachers across the country download it. And it's very targeted toward urban areas of the country.

MS. NALUBOLA: Thank you very much for your comments. I think some of the examples you've given, your experiences would be very useful for us. How do you specifically reach your audiences? Dietitians or doctors and what specific mechanisms do you use? You gave examples about I think Farmland and the Discovering Farmland movies. Are there specific mechanisms that you use?

MR. KROTZ: Sure. Social media allows us to do so much today. The way that you can target specific consumers based on the title that you have in your Facebook profile allows you to go after and target educators, say, in the San Francisco area. You can go after folks that have chef or culinary. You can target

individuals very, very effectively today, particularly on Facebook. Other social media platforms allow you to do the same.

We also work to collaborate. A great example is our efforts with registered dietitians and nutritionists, and organizations like Foodfluence, and making sure that we're able to have a captive audience, but an arms-length audience with groups like dietitians groups and others. In the wellness community, we're just kind of dipping our toe into that right now, but we know it's important and we want to share information on all aspects of food production with that group, very, very influential group as well.

MR. McKALIP: Thank you very much. Next on the list, Jessica Denny will not be here. So we're going to go to Michael Carvalho with Carvalho Farms of Crows Landing, California. Michael.

MR. CARVALHO: Good morning. Thank you. My name is Michael Carvalho. I am a fourth generation dairy farmer in the Central Valley of California. I have a Dairy Science degree from Cal Poly University, San Luis Obispo. And I live on my farm with my wife

and two young daughters.

As a dairy farmer, I appreciate efforts by FDA to educate and better inform consumers about benefits and safety of agriculture biotechnology or GMOs.

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

The majority of animal feed today comes from plants that have some beneficial trait it has received through biotechnology. I believe it’s important for consumers to know what this technology has meant to me and my fellow farmers.

The environmental footprint of farming has significantly improved, whether we are talking about lower greenhouses gas emissions, lower fuel use because of fewer trips across the field, or improved soil health because of less tillage. These benefits

are very consistent with things consumers tell us are important to them. 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 how GMOs help do that. It is up to us to first listen to them and second, to share our stories to help them understand.

Although milk is not bioengineered and exempted from required labelling or disclosure, dairy farmers are concerned about widespread food marketing against GMO technology. Many food companies are labelling and promoting products as non-GMO and as a result are reinforcing confused consumers that GMOs are something they need to avoid.

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

But as a dairy farmer I know the importance of telling the story of my farm to my neighbors and

community. I hope FDA will be able to work with real people and real stories who can help reach consumers with accurate, trustworthy information that is grounded in science. Thank you.

MR. McKALIP: Great. Thank you so much, Michael. Any questions, clarifying for Michael from members of the panel? Thank you very much. Next Elizabeth Eilert from Woodacre, California.

MS. EILERT: Good morning. Hi, I'm Elizabeth, and I'm so nervous I'm going to have to picture all of you naked because that's what they tell you to do when you're speaking in public.

MR. McKALIP: That was a Brady Bunch episode, wasn't it?

MS. EILERT: Yes. So I am another just a mom here. And an interesting thing that I notice, it seems to be all men representing big agricultural companies speaking up here, and all women representing these sort of, I won't say anti-GMO, but that side of things, and I just – I've been sitting at the back of the room sort of remarking what's going on that's interesting. I don't have prepared comments because I

did not have time, but thank you for the opportunity to be here.

I have so much information in my head because I have done a lot of research. I am a single mom responsible for feeding my family, solely responsible, and I care about the food my child eats, and I would assume that everyone in this room and across this country does as well.

So I started researching, and I happen to have two Bachelor's degrees from Stanford and an MBA in Marketing from Kellogg at Northwestern, and I believe I have a decent ability to understand the information that I am reading. So I went to the USDA website and I read the FAQs, the frequently asked questions. And it was very clear to me, based on my research, that the USDA is just a mouthpiece of big agribusiness. I was frankly appalled at what I read. And I would ask in answering question number one, to reiterate what a couple of other people here said, to tell the truth on your websites, all three organizations. My impression is that you are not representing me as a taxpayer at all and a consumer of

food, because some of the details of what I read, for example, let's see, here's a quote. Some crops are engineered to be resistant to diseases or herbicides, making pest and weed control more effective and thereby decreasing the use of pesticides.

That is not my understanding. My understanding is what this woman who spoke previously said, that the weeds become resistant and so you actually need to spray more pesticides. And my understanding, this gentleman said, he just said he's decreased the use of insecticide by using GMOs. Well, let's look at the cost of that. My understanding is animals who eat GMO feed, for example pigs. Their guts are ruined. For example the BT toxin let's say. It's ruining the guts of those animals, and my understanding is the pigs who were taken off GMO diets, GMO feed, got better. They were sickened by GMOs. So if GMOs are doing that to the intestines of pigs, what are they doing to our intestines? And if BT for example, the BT toxin as one example of genetically modified foods, is designed to explode insects and kill them, what is it doing to our guts?

We have the cheapest food in the world in this country, and we have almost the sickest, if probably not the sickest population and the highest per capita spending on healthcare. Do we think there is a correlation there perhaps if we step back and look?

My impression as a fairly informed mom is that our food supply is being poisoned. I heard a medical doctor who used to create chemotherapy drugs, and he now has his own lab and no longer does that, and he overlaid cancer rates on the contiguous United States map and found that the highest rates were in the lower part of the Mississippi Delta, where all the glyphosate drains. And the higher amounts of glyphosate are found in the southern part of the Mississippi when they did sampling.

Now, it’s interesting that in the mainstream media one does not hear about this kind of information so much. And when I saw your websites and I hear this one gentleman who says he’s funded by or his group is funded by Monsanto, BASF and Bayer, that really scares me as a parent feeding a family. It scares me that I

will not know what is in my food. I read every label that comes into my home. I eat all organic and non-GMO in my home and would like to continue to do so. But my understanding is the governing boards that determine the labelling of organic and non-GMO have started to be infiltrated by Big Agribusiness. That concerns me because I do not think they represent me and what I want to put on my table. I really don't.

And most change in this country, if you look back in the history of our country, at least in the more modern times, most change starts in California. Typically we lead the nation, and I guess that's why you have chosen San Francisco to come to. Most change starts here, and I can tell you from my network of Stanford, Northwestern, having worked at places like Bechtel, Coopers & Lybrand, IDEO, I have a vast network of people who I know and talk to, and I have cousins who are dairy farmers and corn farmers in the center of this country, and I talk to all of these people, and they seem to be all anti-GMO, not based on emotion, but based on frankly seeing how sick their kids are, and they take their kids off the GMO diet

and the kids are better.

I heard one story of a six-year-old boy who had terrible ADD and ADHD and acting out problems, and parents got a call every day from the school. After one week on a non-GMO diet, that child was better. No more ADD, no more ADHD. We have a nation full of medicated children and teens, Ritalin. When I see that, I am just appalled. That's abnormal. What is the reason for that? Could it possibly be that these genetically modified foods have not been adequately studied? Could it be that primarily the studies have been funded by people with interests who will benefit from the sales of those products? It seems very obvious to me.

So what I'm sitting here listening to, frankly appalls me and scares me, and I would ask that if you really want to be on the, what I think is going to be the right side of history, because the tide is turning, start telling the truth on your websites. Start telling the truth.

I get the feeling that you're actually out here and you chose San Francisco specifically because

we're known as the probable center for the most anti-GMO feeling. I feel like you're here to just get information from us that you figure out what arguments to use against us in your information campaign. That's how this whole thing feels. Because when I look at the list of who's attending, it's primarily big industry and big corporations. It's not just moms like me, and I think it's about time you really start listening to the people who do the feeding of the rest of the families in this country and the children, and that is the moms primarily, or the parent. I should say parents. I shouldn't just say moms. I don't want to stereotype.

So I would ask in answering number one, start telling the truth. And please know that the tide is turning and there are plenty of us out there who see that what you're saying is influenced by the wrong audience in my opinion, that does not represent as many people as you have heard claimed here so far. Because I know I represent more than just me because the network of moms is very underestimated in this country. We all talk to each other, and we don't like

not being able to know what's in our food. So the labelling is clearly an issue.

Things like gene silencing and gene editing. My understanding is there are movements to get those to be called non-GMO to qualify for that. How disingenuous is that? Of course those are genetically altered. I don't want to eat those.

The nation of Hungary burned all of their GMO crops. At least that was a couple of articles that I read, and you just saw the EU vote where Europe did not renew the license for glyphosate. And I think we're all familiar with what's going on with the glyphosate argument.

So I would ask, that was question one. I don't have an answer for question two, how consumers get their most information. I did my own research. A lot of people don't have time to do that. So if you really are going to represent the people of this country, represent others, not just big industry in the information that you disseminate.

Question three, let's see. What was that? Yes, that was disingenuous as well. How can the FDA in

coordination with the USDA best reach consumers with science-based educational information on this subject? When I read that, I guffawed because, again, most of the science that I have seen on this subject has been funded by big agricultural companies or big pharmaceutical companies who have a vested interest and stand to benefit. I do not feel that they represent my interests in what I eat at home, nor any other individuals. They seem to be self-interested.

So I would ask that you use real science, not the science that's primarily been funded by interested parties. I would look for neutrality and real science, not skewed. And again, using disingenuous things like trying to hide gene editing and gene silencing as being non-GMO.

Clearly I could go on for a long time and I will stop now, but I think you get the gist of what I'm saying. I am really scared by what I hear in this room, and I am disappointed that there aren't more people like me. A lot of people are scared to speak out because they see what's happened to scientists who speak out. They get silenced. They get threatened.

There are scientists out there at universities who have done the research, and they are discouraged from publishing for a lot of reasons. So people are afraid for their safety actually from the interests of very big corporations. So thank you and I do think the tide is turning. I do think you guys will be on the wrong side of history if you continue to promote genetically modified foods so much. Thank you.

MR. McKALIP: Thank you, Elizabeth. Really appreciate your comments. And if you were nervous, you didn't show it at all.

MS. EILERT: Well, I'm angry. I'm angry, that's why.

MR. McKALIP: I understand. Just to be clear, and we're parents up here. We care deeply about the food. We wouldn't be here if we didn't. And it's areas that we selected to do a session on each coast. One in Charlotte, which isn't quite the coast but the East, and to do one in San Francisco. We wanted to encourage as much input from all over the country, and received several hundred comments to the public docket even before we started the listening sessions. So the

reason we're here, we want to gather as much as possible. We want to take that back. We want it to be part of our process going forward. So what you said and what you shared is important, and we are here to listen. We want to make sure that we're able to incorporate all views into our actions moving ahead. So thank you.

MS. EILBERT: That would be great. And your websites and information campaign need to reflect that then, because they currently do not.

MS. NALUBOLA: I want to echo Doug's comment. Thank you very much for being here and taking the time and providing your comments, and also we say as a parent, I can definitely say that I share your interest in making sure that the foods that we feed to our kids, all parents agree with you on that. So I think the reason we chose California is because we wanted to have a wide range of perspectives to be informed by. We chose two meetings. One on each coast. And also wanted to do something outside of the immediate D.C. metropolitan area to actually get out and go to different locations in the country.

And you mentioned that you've been on our website. I'd be interested in your feedback on whether you found searching through our website helpful, because I know myself, our websites are not always all that user friendly, and in addition to your comments about the actual substance on the websites, how was your experience about looking through information and sifting through information on our website. That would be helpful. You don't have to provide comments now, but even in your written comments if you have concrete examples of how we can do better providing more user friendly information that would be helpful.

MR. McKALIP: And we can visit with you offline as well if you're able to stay and discuss the website and your experience.

MS. EILERT: Yeah, I don't think anybody would recommend looking through government websites of any kind frankly. All right.

MR. McKALIP: Thank you, Elizabeth. Appreciate it. Next up, Chad Niederhuth from Sacramento, California.

MR. NIEDERHUTH: Hello. Thank you for this

opportunity. I'm a plant biologist and an educator, formerly a post-doctoral fellow at University of Georgia soon to be assistant professor at Michigan State University.

I've been familiar with this debate for a long time, and it still continues to amaze me that even teaching at the university level the degree of misunderstanding there is about this subject, and that's reflected nationwide really by the huge gap in understanding between scientists and their opinion on this subject where there's a large consensus regarding the safety and utility of these crops versus the general public.

And so in trying to communicate the science effectively to the public, I think it's important that the FDA really base its methods on a science-based approach. So look to the vast body of scientific literature and growing body of scientific literature on communications and especially in the communications of science, and really use that to guide your approach in communicating to the public.

In terms of trying to address what issues

are important to consumers, I think you've heard many of those today. There's a large concern about the safety of these crops, about the effects on the environment. So I think that the information that you provide should first address the concerns of the consumer rather than trying to explain just the science. You should be targeting a way that really gets to the heart of the real questions that people are trying to ask.

In terms of where consumers are receiving their information, unfortunately so many consumers I'd say are getting their information from the internet, getting their information from other individuals who are oftentimes themselves misinformed on this subject. And I don't know if you've spent much time on the internet trying to look up this subject, but there is just pages and pages of misinformation, oftentimes pushed by organizations and individuals who have ulterior motives seeking to misinform the public, generate fear, and oftentimes use that even to generate profit for themselves from various scams. So there's no way to really get around that or eliminate

that misinformation out there. So I think it is important then that the FDA provide a comprehensive source of information to counter that.

In terms of how to communicate that, as I've said, you should be based already on the body for scientific information out there, on how to communicate to the public. Great examples include the Center for Food Integrity, which has done a lot of work in studying these issues, surveying consumers, and getting at what methods are most effective in communications. I think you've already heard it mentioned today, this difference between a trust-based model versus a deficit model of really it's not enough just to provide facts and information, but you also have to be appealing to what the concerns of the consumers are. Going, taking a values-based approach of really understanding what do they value most and how can you answer and address those values.

And also at all times, please this should be a very transparent and open process, as that is essential to gaining the public's trust.

With that, I'll just wrap it up and thank

you for this opportunity.

MR. McKALIP: Thank you, Chad. Panelists, any questions or clarification? Thanks. Mark McAfee with Organic Pastures Dairy Company out of Fresno, California.

MR. McAFEE: Thank you. It's indeed an honor to be here. My name is Mark McAfee. I'm CEO, they call that the Chief Excitement Officer or Chief Educational Officer, at Organic Pastures Dairy. It was founded in 1999. When I started attending farmers markets and talking to moms just like we heard today, I checked the boxes. I said, what is it you want from a dairy? And they said, well, we don't want GMOs. Click. That's one box. We don't want pesticides. Click. That's another box. We want to be able to visit you and see what you do with your cows and pastures. So check another box. It went down and down and down. We want certified organic. We want certified humane. All the boxes I checked when we started our dairy.

And in the voice from the moms, you heard them today. They said, we're feeding our children. And when we feed our children, there's got to be an

integrity and a trust that what we're feeding our children is good for them. And I took that very solemnly, emotionally back to our operations and founded that now the third ranked brand of organic milk in the United States with 650 stores, 22 trucks, 100 employees, founded in Fresno, California. I invite each of you to come visit us. It's a remarkable thing. I am completely consumer connected because I don't sell my milk to a processor. They wanted that milk raw. They wanted it unprocessed, just like their own breast milk, so when their children went off breast feeding at six or seven months could thrive instead of having digestive upset and allergies to processed dairy products and to formula.

The FDA doesn't agree with raw milk. They hate raw milk. California has had raw milk legal forever, has very strict standards, and I would beg the FDA to look at standards for raw milk for everybody across the United States. It's not because raw milk is so great. It's because the Department of Energy in the 1990s spent a lot of money to help us. The Department of Energy isn't here today, but they

wanted to know something about the human genome. They wanted to know the long-term effects of radiation on human beings. And together with other organizations, the NIH, they put together $4 billion and in about 15 years they figured out that we are bacterial sapiens. We are not really made up too much of human genetics. There's only maybe 25,000 genes you get from your parents. The majority of our genes come from bacteria. Now that's a profound finding to find out that that happened in 2003, but that's only about 13, 14 years ago, but we're still on a pathway to really underserving the genome that makes us human, and that is the 98% of genetic information that drives us to be healthy and human is actually from bacteria.

If you look at antibiotic abuse, if we look at Roundup, it's interesting. I sit as the delegate for California at the National Farmers Union. I've been there for the last five years. I'm also on the California Dairy Campaign with a lot of provincial dairymen, and I'm one of their executive directors.

I've also been a Flying Doctors of Mercy LIGA pilot to Mexico, humanitarian medical flights for

many, many years. I was a paramedic for 16 years. I am deeply engaged with trying to make good, positive change. But what I'm finding is that the positive change is not going to come very easily because farmers and consumers are completely disconnected. We've heard this resonating throughout this entire conversation today.

I'm not disconnected from our consumers. I actually have a retail store. We sell directly to consumers. We sell at 25 farmers markets every week, direct with consumers, moms that ask me hard questions and come to visit us, and 650 stores that are thriving selling our products. And our products are not sold at less than production cost. They're actually sold at a premium, and we can't keep them in stock.

There's a secret sauce to what I've said here today. And that is, instead of rejecting the moms that wanted to have safe foods for their children, I'd embrace them completely. And in embracing them completely, I have complete integrity online when I speak. I have complete integrity what I've said about the human genome project and what the NIH and the

Department of Energy has discovered about us being bacteria sapiens. And what I say about Roundup and GMOs is profoundly true. I don't have an integrity problem.

Interestingly enough, there may be some GMO crops out there that are perfectly fine. Perfectly fine. But how are those GMO crops actually used, and how is the application of that GMO crop? It allows that GMO crop we're talking about today, just referenced on, Roundup Ready, allows the mass application of Roundup which is now understood to be an extreme gut disruptor. It's found in the European Union it's been banned now but you can buy it at Home Depot here in California.

So a severe gut disruptor that's being applied to our crops and put into our food chain as a drying agent on grains, as a spray that goes on alfalfa given to our cows and other crops, it ends up in our food chain. And if you know about the human genome project, you understand the human genome in terms of what we want to do in our villi of our intestines, you have to start scratching your head

saying, there's no wonder that moms are objecting and saying not on my food today.

They want clear labelling of products that are including a GMO ingredient. They want clear understanding what organic means. They want to be able to visit their farmer. What we have is a complete disconnection between farmers and consumers. And what I find very unique when I go to these national conferences is that you can divide the farmers into two groups almost like a perfect line. Those that are connected to their consumers and listen to them and provide food directly for them and feel responsible for them; and those that do not.

And the ones that do not, they're not bad people. They're hard-working, intelligent, smart people, but they just don't have any connection to what the consumers are concerned about because the opinions of the farmer directly correlate to the next partner they have in their food chain. If your next partner in your food chain is your best friend who sells some kind of a Roundup Ready seed or a broker that pays your commodity price or a processing

company, then that's who you're going to believe in and that's the faith you're going to have. But if your partner is a mother that gives you a hug and a kiss and thanks you and gives you a great story about how your raw milk helped them and their families to thrive, and you're paid well, wow, what a difference.

So in all fairness, if you're looking for integrity, and I'm serious when I say this. I'm very serious when I say this. I'm not joking. Round up everybody you've got in the FDA that is sold out to big industry and have them arrested and removed. You will have every mother in America loving you. Because the integrity comes from the fact that there's collusion between, it's just part of the culture that the FDA is a voice of industry. And today what I gather from this is you're a marketing department of the industry that wants more GMO, when it's being solidly rejected by the consumers that are very, very smart. And the internet can probe deeply and look at the European Union studies and look at the PubMed studies and NIH studies that are on your websites, and very intelligently peer-reviewed published articles,

and understand what's going on with the gut, and say, not for my children, not in this lifetime.

I'm a grandfather with six grandkids, and their health and the health of our consumers is the most important thing in my life, and I'm dedicated to that, but I'm passionate about it. And that passion and that integrity rings through to the fact that if a vibrant brand is consumer connected, and I would ask you to search inside your soul to look for a different place to find integrity. Thank you very much.

MR. McKALIP: Thank you, Mark. Any clarifying questions from members of our panel?

[Applause]

MR. McKALIP: I appreciate your comments. Thanks so much.

MR. McAFEE: Take them home with you. It's very important.

MR. McKALIP: As we will all the comments. Thank you. Next up, Elisa and I apologize if I don't get names perfect, Odabashian from the Consumers Union Consumer Reports here in San Francisco. Was I close on the pronunciation?

MS. ODABASHIAN: That was really good. I've heard much worse. Good afternoon. Thank you. My name is Elisa Odabashian and I am the Director of Strategic Initiatives in the West Coast office for Consumers Union, the policy division of Consumer Reports. Appreciate this opportunity to comment on the Educational and Outreach Initiative that FDA has been tasked with.

Consumers Union is, as I said, the policy division of the nonprofit Consumer Reports, the largest consumer organization in the United States, reaching more than seven million consumers through its print and online publications, and engaged with more than 1.5 million consumer activists concerned about policy issues.

We have long advocated for pre-market safety testing and labelling of GMO foods. As Consumer Reports national surveys year after year have shown that an overwhelming percentage of consumers, upwards of 90%, say they want to know if the food they're buying has been genetically engineered.

On the issue of specific topics consumers

would find useful, in calling this public meeting, FDA's notice indicates that it aims to educate consumers with science-based information on environmental nutritional food safety economic and humanitarian aspects of agricultural biotechnology. These are all issues of interest to consumers.

First it is important to acknowledge that consumers have been bombarded with information on biotechnology, a good amount of which has been distorted in order to influence public opinion and the political debate about the technology and over the value of labelling genetically engineered foods. In part, as a result, there is much public skepticism and distrust of what is said by almost anyone on this topic, including by scientists. It will be FDA's task to first assess what really qualifies as reputable science-based information in these areas before communicating to the public. If FDA is to truly educate consumers, it must be rigorous in this assessment. And where issues are not settled science or where misinformation has been widely distributed, FDA must address this directly.

Here are just two examples where misinformation about GMOs has been disseminated by the media. One from the environmental area, and another from the economic impact area. For consumers one of the most important environmental issues is pesticide use. Time and again in public debates over safety and labelling, it has been said that genetically engineered crops reduce pesticide use. This is a false statement. Adoption of genetically engineered varieties in two crops, corn and cotton, have reduced insecticide use. Insecticides are one type of pesticide. The herbicides are also pesticides, and in the years since herbicide-tolerant genetically engineered varieties of corn, soy, canola and other crops have been introduced, the use of the herbicide glyphosate, also known as Roundup, has increased more than 15 times over.

Taking this into account, overall agricultural biotechnology has vastly increased, not reduced, pesticide use in the United States. It will be important for FDA to address this issue with a clear presentation of the scientific facts.

An economic issue that is of importance to the public is the oft repeated promise that genetic engineering increases crop yields. This claim, too, is false. The National Academy of Sciences in its 2016 report on biotechnology dealt with this question directly. The report concluded that GE technology itself has not led to significantly higher yields. Noting that, and I quote, “There is no evidence from USDA data that GMO crops have substantially increased the rate at which U.S. agriculture is increasing yields.” Again, it is important that FDA presents the data in this case crop data, in a way that informs the public in a non-misleading manner.

The other topics on which FDA has been tasked with educating the public are almost as difficult and controversial. Food safety is clearly one. While there is no strong evidence that genetically engineered foods currently on the market pose widespread safety hazards, there have been many highly oversimplified claims about its safety. In fact, genetic engineering does carry risks. For this reason, FDA requests developers of new GE foods to

ensure that there have been no changes in allergenicity, toxicity or nutrition, or other unexpected effects that could impact safety. FDA has an obligation to educate consumers on this point.

On the flip side, there have been unsubstantiated claims that genetically engineered foods are responsible for everything from accelerated aging to autism. These claims are also poorly documented, if at all. FDA must endeavor to present a balanced and science-based view of this issue.

In two other areas it appears to us that there isn't much science-based information available. In the area of nutrition, which is always of great interest to consumers, we are aware of very few products of agricultural biotechnology currently on the market that have actually improved the nutrition of a food. Nor have there been good studies of whether GE varieties may have inadvertently become less nutritious.

An oft-cited example of a nutritional improvement is golden rice, a genetically engineered rice variety that contains *beta*-carotene, which the

body converts to Vitamin A. Golden rice was developed in the laboratory, but still after more than a decade of work has not been commercialized. Recent reports suggest that it may never be commercialized since in the process of engineering the changes needed to express *beta*-carotene, additional and unexpected changes occurred that stunt plant growth and reduce yield. It would be helpful if USDA could point to good scientific data in this area. And if consumers are to be well informed, it would also be extremely important for FDA to refrain from repeating speculative theoretical and self-promotional industry claims as to the potential of genetic engineering to improve the nutrition of food.

As to the humanitarian impacts, we are aware of even less data. While industry has made widely repeated claims that biotechnology will feed the world's burgeoning population, these claims appear to us to be less fact-based and more public relations speculation.

MR. McKALIP: One minute.

MS. ODABASHIAN: Polling data suggests that

one of the biggest sources of information on food is family and friends or peers. Other obvious sources are traditional and social media. On the GMO issue in particular, trust of information sources has become a major concern. Consumers are smart. They do not want to be talked down to or told what conclusions they should make. And they want to make their purchasing choices based on substantiated scientific information.

We believe that FDA has a challenge ahead of it in its task for three reasons. In a number of these areas the science is hotly contested and not settled. In other areas the science has been misrepresented. And in still other cases there is little science at all.

I say this as a representative of Consumer Reports, an evidence-based organization that uses science every day in its testing laboratories to inform consumers about the safety and efficacy of products and services from which TV has the best sound system to which dishwasher cleans the best to which rice product contains the least arsenic to which cars are the least likely to roll over.

So in conclusion, biotechnology is a contentious and concerning issue for consumers. One of FDA's most important tasks will be to strengthen its credibility with consumers to the information it chooses to disseminate. It will require taking a balanced approach providing the public with scientific evidence, admitting where the scientific data is conflicting, pointing out where controversial claims have been made that are not true, and excluding claims based on public relations. Thank you.

MR. McKALIP: Thank you very much, Elisa. Any clarifying questions from the panel? Appreciate it very much.

We have had two additional individuals sign up to give remarks, and we're going to recognize them at this point. I will first turn to Irene Fay with Jeff's Naturals out of American Canyon, California. Irene.

MS. FAY: Good afternoon and thanks very much for allowing additional speakers. I think there's two things that come to mind when I heard about this meeting. And by the way, I heard this through one of

the leading natural food distributors, UNFI. I don't know if you're familiar with them. But there's two companies in the United States that are considered the top distributors. UNFI is one of them and the other company is KeHE. These are two great sources for you to get in touch with, to find out more about how consumers learn about their foods. I think they're advocates for clean food. They sell natural foods, and they've been very interested in the whole subject of GMO or non-GMO. So that's just something you might want to jot down.

I think there's two questions that I would ask myself. Is one, how do you disseminate the information which you're asking, but two, what information do you disseminate? Now when you ask yourself what do consumers want to know, there are several sources to ask. I was so inspired by the last gentleman who talked about going to farmers markets and talking to moms and checking off all of those boxes, because those are the people that consume the food that your organizations regulate. We are the voice.

There are a number of organizations that you can touch. Let me just give you a couple of them. The NCG, which is the National Co-Op Grocers Association. Those are retailers who belong to this organization, and they're all natural food stores.

There's another group called INFRA, I-N-F-R-A, that's the Independent Natural Retailers Association. Similar to the Co-Op Association, but these are independent retailers.

There are also a number of stores, chains that you can talk to, who service primarily consumers who are concerned about what they put in their mouths and what they put on their table, Whole Foods being the top retailer which I'm sure you folks are familiar with. They have initiated a labelling process that anyone who sells to their stores will have to conform to by September of 2018, and that means that you will either have to put a label on your product that says that it's non-GMO or it is GMO. And that will help consumers decide what they want to buy and they'll speak with their dollars.

The second two largest natural food stores

are Sprouts Natural Foods. I'm sure you've heard of them. If you haven't, you're here in California. It's a good time to stop by. And another firm called Natural Grocers, which is an organization that owns upwards of 100-plus stores.

So those organizations have about a thousand retail outlets, and their consumers that shop there are the folks that you probably want to hear from. And they're probably also the people that you'll want to disseminate the information to. So I strongly recommend that you reach out to these organizations and ask them the very same questions you've asked today. Is how do you reach out to the community? How do you get that information out there? They could be very helpful. But they could also be very helpful in helping you understand what it is the consumers want to know, because their consumers ask them. And they in turn should be asking you.

If teachers, educators, nonprofits and those who benefit from GMO manufacturing, Monsanto, DuPont, etc. can communicate directly, honest byproducts may result. But you have to have both parties come to the

table. You cannot simply ask how do you disseminate information about GMO products without asking the question, how do you disseminate information about non-GMO products. You cannot educate the public about only one side of the issue. It's dishonest. It's not what we pay our taxes for. It's important that you open this dialogue, and it's important that you speak for and to everyone.

In closing I would say that pro-biotech information oftentimes polarizes those who are concerned about what they put in their children's mouths. I personally when I hear the names Monsanto or DuPont get very nervous. And if you don't, that makes me even more nervous. Thank you.

MR. McKALIP: Thank you very much, Irene. Appreciate that. Any questions for Irene? Thanks. Last but not least Peggy Lemaux with the University of California at Berkeley. Peggy.

MS. LEMAUX: Hi. Thank you for making room at the end for me to present my thoughts. I am a mom. I'm going to come at it from a slightly different perspective. In 1987 my colleague at UC Berkeley,

Professor Steve Lindow, attempted to conduct the first test of a genetically engineered organism, the ice-minus bacterium, which was intended to prevent frost damage on crops. The first effort took place in Tulelake, which is a small farming town in northern California near the Oregon border. The engineered bacterium was sprayed onto the potato plants by scientists who were wearing respirators and disposable protective coveralls, and the EPA agents were up on ladders checking monitors to make sure that the bacteria didn't spread beyond the field.

While the protective clothing was intended to protect the researchers, it probably appeared to a lot of the passersby which might have been mothers and fathers taking their kids to school, like it was some sort of toxic cleanup. As you might imagine, the scene was not welcomed by local residents because the University hadn't prepared them for what was going on in this countryside.

Another attempt by the University was to do the same testing in Monterey County, and they responded in the same way, despite the efforts of

Professor Lindow and others at the University to help them understand what was going on.

At this point the University of California thought, hmm, maybe it would be prudent to actually have somebody whose responsibility it was to proactively go out and provide information to the public about this new technology of doing a genetic modification. That individual was me. I started as a cooperative extension specialist at UC Berkeley in 1991, and my job was to do what you're saying there, agricultural biotechnology education and outreach. So I started in 1991. We're in 2017 and we're having this same discussion about how you go out and talk to people in the public.

So my job description is pretty wide. It involves duties that include both research and outreach. And what I do on the outreach side involves our statewide leadership, that's what cooperative extension does, my job is statewide, to develop educational programs aimed at providing fact-based information on agriculture, food and its technologies. So talking about all kinds of things that have

influenced agriculture over the years, classical breeding, marker assistant selection, genetic engineering and organic practices.

In addition, I provide fact-based information to promote sound policy decision-making to foster the development of appropriate regulatory structures at the local, national, and international levels.

I just want to say that cooperative extension, many people don't know what it is, but we are located all over all of the states in the United States, and our job is local, so I have colleagues in every county in California. So someone mentioned, what are ways to reach people like dietitians and chefs and so forth. Cooperative extension is an arm that can be used to do that.

In order to perform these functions without being beholden to commercial organizations, I run my outreach program using only public funds. I've not taken any money from corporate entities. Upon request, I give lectures to a variety of different audiences that range anywhere from, as we mentioned, dietitians,

growers, lawyers, teachers, and I also work with other public sector scientists to develop educational programs and materials for end users and practitioners. These include things like after school curriculum which are developed for middle school students and also for 4H. And also I have a bunch of educational displays and games that we've developed over the years, an extensive slide archive and videos. And I also wrote on request two peer-reviewed Annual Review articles in 2008 and 2009. And I was asked to do this, and they said, take – so I've been doing this for a long time – take the questions that people have asked you and try to answer them in the most fact-based way that you can. And so I linked all my answers to the scientific literature as best I could.

So largely these efforts have been limited to those of myself and my long-term administrative assistant. In 2015, with funding from the University of California Global Food Initiative and the Berkeley Food Initiative, I was able to establish two different efforts. You heard from one student this morning in a CLEAR project which is Communication Literacy and

Education for Agricultural Research, and the Millet Project, which is looking at introducing ancient grains into the food system.

So in both cases these efforts are motivated not by me but by the interest of the students. Primarily they're undergraduate and mostly graduate students and post-docs. And really until the last few years interacting with the public about science issues, there were only a couple of students who were actually really involved in that, and almost no faculty were. Only in cases where their job descriptions actually required them to do that.

And I think talking with the students now, they're really sort of faced with a skeptical public that often doubts the values of what scientific research does. And so the students have really become motivated to go out and explain what they're doing and why it's important in a language that the average person can understand.

In the case of these UC Berkeley students, it really doesn't imply, and I think Daniel presented that, it's not a yes or no thing, or a right or wrong

thing. It's really they're just listening to what people have to say and trying to look at how people see the issue of science in a very complex way.

We see this in areas aside from just biotechnology. We see it in people's understanding of vaccinations, of weather extremes, of fluoridation. So there are lots of things that people are concerned about over and above this biotechnology. And students are aware of that. And they're able to go out and listen to people. And so one of the things that the students have done is to go out to places, because they said, if we could stay in the classroom or stay in the laboratory, we don't hear what people have to say. In fact, one of my students gave a talk at the Berkeley Library, and she said that's the first time I've ever heard what people really think about GMOs. And so this is one of the ways that the students are going out now. So they go to farmers markets. They go to the public library. They go to zoos. They go to wherever they can find. They go to bars actually and talk to people there.

And so they do this because they feel that's

a way they can have meaningful discussions with people and really find out what's driving people's concern. And so they can, by doing that, sort of develop an empathy for what people are thinking about, and they hope in that way to develop some kind of constructive dialogue that they can use to reach out to people about what they do and science.

So I think if this initiative is going to be used proactively to provide information to the public about these new technologies in agriculture and food, you want to avoid the situation that happened in Tulelake. You need to be out there. I mean this is a perfect example of communication not being there, and really not helping people to understand before something happened.

So from my years of experience doing this kind of thing, and also watching the motivations of CLEAR students, I would suggest to the FDA and the USDA to move forward with this effort with open dialogue, listening to different opinion and different options, trying to extract the best ideas to shape the future of agriculture.

I've been saying this for over 25 years, that we need to take whatever is the best out there and bring it together. And it's not just one approach or another approach. There are positive things about different ways that people have talked about today, and about the way we can approach agriculture. I think that by listening to all these voices, which I try to do, and take those best ideas and the best practices, and pull them together to mold the most sustainable agriculture that we can.

So I would really encourage you to look to cooperative extension and also to look to young students who are the ones who can go out and talk to people. They haven't necessarily formed their exactly how they want to think about the future of agriculture, but it helps them to go out and talk to the public about what their concerns are. So I thank you very much for this opportunity.

MR. McKALIP: Thank you very much, Peggy. It was not by design. We didn't even know you were going to present today, and that you'd present last, but you did a really good job of kind of summarizing a lot of

things I think we heard from a lot of the folks in the room this morning. So thank you very much for that. Any questions for Peggy from the panelists?

Ayma, any questions that have come through the webcast?

[Inaudible comment about opening it up for questions]

MR. McKALIP: Yes, please do that.

CLARIFYING QUESTIONS AND FOLLOW-UP ITEMS

MR. McKALIP: At this time, we have a few minutes I think before we wrap up. Based on some themes that we've heard for the panelists to ask some additional questions, and if you're interested in addressing them, just come up to a mic. This isn't a ten-minute thing; this is more of a couple-minute thing on thoughts that you have.

But one thing I heard from many, many presenters here this morning was the use of social media, and I think another theme we've heard is that our websites aren't currently doing the job in terms of providing info out there. So I'd be curious. I know Karl brought this up, but really if anyone would like

to step to the microphone and just provide any further perspective for us up here, for EPA, FDA, USDA on how we could employ social media in a new or different way than what we currently are, especially on this topic of Ag Biotech. So if anyone would like to come up to the mic, we'd be interested to get some additional comments on that. Because that is a theme that we heard a little bit from in the comments but didn't necessarily fully flesh it out in the session so far this morning.

Please restate your name so the folks making the transcript know who's speaking.

MS. FAY: Sure. My name is Irene Fay and I'm with Jeff's Naturals. I would direct you to the Project Non-GMO website. It's a really good example of how to put information out there in a very readable and accessible way.

MR. McKALIP: Thank you for that, Irene.

MR. REYNOLDS: Doug, I might broaden it to, you know, we got a couple commenters who were questioning how as regulators we could better interact with consumer groups. So along those lines, social

media I think is one possible approach. But if there are other techniques we could use that we're not currently using, I think it would be helpful to hear those as well.

MR. McAFEE: One thing I've heard – Mark McAfee, Organic Pastures. One thing I've heard, and I've experienced is it's really hard to connect with and talk to regulators. It's almost like a frozen, there's a barrier. There's no way for the public or even producers to actually connect with USDA or connect with FDA. It's very difficult. If there was a way to have some kind of an outreach link with legitimate voices that could be heard both back – more communication so that concerns or ideas or rational science being brought from some other part of the world, INGC, stuff from UC Davis, to be shared, and actually absorbed and taken home. That would be really powerful.

Because I think that one of the things that we find that I hear all the time from moms is, it's so frustrating. There's nobody to talk to. There's nobody to share with. There's nobody to connect to. There's

this wall. And we need to tear down that wall if you want to increase communications, and the communications need to go both ways.

And on social media you get that communication both ways. But the FDA doesn't, so I would challenge you to go on social media websites and actually say, this is Ritu Nalubola, Ph.D., M.D., or whatever you are, as a doctor, and say, you know, I'm wanting to engage your thoughts on this subject. And put yourself out there. I know that's really hard to do. It may even be impossible to do. But boy, that would be really a revelation in terms of consumers wanting, there's somebody that wants to talk to us. That's a powerful thing.

MS. NALUBOLA: We do have, I mean I just want to thank you, Mark, for those comments. I think we just want to point out that on our website, and I know our websites are not all that user friendly for the most part, and it's hard to find information. I can completely understand that. But we do have a place where stakeholders, consumers, anybody, the general public can submit inquiries. There's the ask CVM web

link. There is also similarly on the food side we have a link there. You can submit a question. It's not specific to biotechnology products. It's about anything that's regulated under by CVM or CFSAN, so we do have those sorts of links. Maybe those are not all that accessible, but you mentioned have an outreach link. What specifically did you have in mind?

MR. McAFEE: Let me make it personal so it's easy. The people in Nevada want raw milk. They can't get it from California. The FDA stands in the way. They won't allow raw milk to go across state lines, even though there's 650 stores in California that have this wonderful raw milk that's produced by five different dairies, they're regulated.

And the citizens petition, administrative appeals process, is submitted, preferably you go through the steps to have a voice for the FDA, and the FDA refuses to respond. It takes federal litigation to get any kind of conversation regarding something that consumers really, really want. That's a great example, and there are many more.

But there's just not that permeability,

accessibility, unless you've got big money and the lobbyists or somebody that's connected to corporate industrial back door avenues to be able to talk. And this could be on a broad range of subjects. Access is really, really tough. So I would -- a softer, sweeter, kinder more consumer-friendly mommy-friendly FDA would be really, truly beloved. I'm serious when I say that. And I'm a dad saying that. I mean, the women in this room and the dads that aren't in this room and the children would really appreciate an FDA that will respond to them, not as a marketing department trying to push an idea, but a listening department that is trying to absorb, digest, and reconcile so that they can respond and be truly the next generation of that future thinking organization which can advocate for health. And look at the human genome project and really bring that in. It's pretty powerful stuff. Thanks.

MR. McKALIP: Are you seeing that listening, human thing today from us hopefully?

MR. McAFEE: You guys are human. I appreciate that. There's dialogue and I appreciate you letting me

speak to you, Doctor, because oftentimes I'm not even allowed to speak to anybody at the FDA. Last time I was at NCIMS, they ran from me, physically. And it's really sad because there should be dialogue to understand. And diversity is our greatest strength in this country. And you've got the raw milk guy, you've got the organic guys, you've got the pasteurized guys. We're all feeding America. It's not good, bad, and ugly. We're all on a team. We have a place at the table, and we all have different perspectives. And it's not that GMOs are bad or wrong. It's just that the consumers deserve a right to know what they're eating, and a further right to understand how it came to pass that this is in their food supply.

The whole story needs to be told. And so I'm just really – it would be great to see an FDA that was approachable. That was more responsive.

MR. McKALIP: Thank you, Mark. I was looking over my notes here, and the very first speaker we had, Daniel Westcott, talked about humanizing this, and I think that's an interesting bookmark. I've worked for U.S. Department of Agriculture for 24 years, and so

many scientists are not necessarily accessible, and it's just their job. They're focused on the science. But they're not necessarily public facing. And I wish I could roll all of them out to have them talk with you about what they do and how they do it. But other overarching – Ayma, any questions that have come through the webcast that we need to address? We're okay?

[Inaudible response]

MR. McKALIP: Okay. From the panel anything?

[Cross talk]

MR. McKALIP: Yeah, please do, and make sure you say your name again.

MS. GERMO: Lisa Germo. I'm wondering why we're giving $3 million of our taxpayer money to this, to say it is safe, when the word safe means nothing in the form of what you guys are doing here.

MR. McKALIP: Sure. Thank you, Lisa. There's clearly a lot of consumer and public interest in biotech. That's obvious from the conversation here today. It's something that we're seeing throughout all aspects of the marketplace. And so – and I think the

federal government has been largely absent from that conversation. Our websites are there, but how much are we really communicating what we do, what our scientists do, to have a more developed conversation. So we now have the resources. It's a good time to do that. And we want to make sure as we approach this task that we've been given by Congress, that we're really incorporating public input and thought into what we need to focus on. I mean, frankly we could sit in our offices and come up with something. You all could've stayed home today and not come to this session, but we would both be missing a huge opportunity here. We want to have this conversation and make sure that this initiative is going to get off correctly on the right foot.

MR. REYNOLDS: I think Lisa's comment feeds into this, but the word I think I've heard most today was trust. And from listening to the comments, I think a good portion of the consumer base doesn't have that trust with the regulatory agencies. And that's probably largely our fault and our not effectively communicating with consumers. So I think that's

something, I know at least from our agency at EPA, something we need to focus on more clearly. Not just presenting science, but when we approve something, we're not doing that at the behest of a big biotech company. We're doing that because we've done a very rigorous assessment, and it meets the legal standards under the law. And I think we need to more effectively communicate specifically what that means in terms of safety, in terms of the environment, and hopefully establish some of that trust with the consumer baes.

MR. McKALIP: What Alan said is true of all three of our agencies in terms of the scientific integrity and what we do in our approach and how much we care about the outcome of that approach. Any other questions?

MS. NALUBOLA: One thing that I, in addition to the ones that Doug and Alan pointed out already, one thing that I think I heard across a number of commenters is really to make these necessary connections between farmers and consumers, making regulators more accessible. It's really building the network and having the relevant entities be able to

talk to each other, learn from each other. I mean, I think there has been a growing interest in biotechnology and issues related to biotechnology. We as our agencies continue our regulatory missions. We've put information out on our website, updated them. I know for FDA we do also consumer and constituent updates to make some of our information that's not always very readable, to put that also in a more plain language type of information for consumers. I'm just wondering going forward, some of the things that came up with the cooperative extension services or some other organizations, how do we as we implement – I think it's one thing to develop the initiative, to develop the educational materials, but to make it more sustainable into the future and to really implement this, who do we network with? Whom do we partner with? What are the different partnerships that would be helpful? The cooperative extension services, maybe working with state departments of agriculture. I'd be interested in thoughts on those.

MR. McKALIP: Any participants like to come forward to the microphone and address Ritu's question?

Jamie.

MR. ALLISON: Jamie Alison again. In simple terms from a teacher's point of view, you can use some of the pieces that are already in place. So for example, a Bio Ohio, a Grow Next Gen that we have in Ohio where we're trying to start these networks. I can only imagine how many of these networks are just struggling around the country to kind of make the connections. But with your influence, your impact, your guidance, we can expand those. We can connect them between states. The more of the resources that are around just through a simple networking, almost like today--I've come across some resources that I'm already going to tap--just continue to build them, and reach out to the ones that are existing. Help us make them bigger, and then once they get bigger, use that as a model for someplace else.

And they don't have to be all one-sided. If it's an educational thing, we've got an obligation to teach both sides. And so the more you bring to the table, the more networking we can do, whether it's virtual or face-to-face, the better off it is. Thank

you.

MR. McKALIP: Thank you, Jamie. Any others? Ayma, last call for anything through the webcast.

WRAP-UP

All right. Thank you again, everyone, for participating. I think we heard a lot from everyone in this room that everyone cares deeply about their food and what goes into it. We heard that from moms and consumers, but we heard it from the farmers, we heard it from not just organic producers but those involving conventional agriculture as well. We heard it from our university and research and education communities. And we care, too, and so do the agencies that we represent and the many scientists who can't sit up here at the table, too. I've never met one who didn't care deeply about the outcome of the food and what it contains.

It's clear I think from hearing comments around the session that you're getting information from a lot of places. And we want to construct this initiative. That's what today was really about, was to help bring some clarity and additional voice from what our agencies are doing in terms of speaking about

biotechnology in agriculture.

So we really again appreciate your participation. If you weren't able to say everything that you came with, you can submit those in writing. We'd be happy to have your comments in writing. In, addition, you can respond to the docket from the Federal Register, those who've tuned in by webcast or those who were not able to be here today, that's spelled out in the packet and in the meeting notice. Again, you have until November the 17th to submit written comments to us. Please do continue to monitor the site as well.

We hope to have the transcript from this session up and available in about four weeks. It does take a little time to have the stenographers do the work and for us to take a look at it and make sure everything is accurate.

The video hopefully will be available in about two weeks as well for folks to see as well. So thank you again. Really we can't thank you enough for taking time out of your busy schedules to participate. Government works best when we have a dialogue, when

we're able to fully incorporate your thoughts, and that's what we're going to do going forward from this session.

So thanks again. With that, we're going to wrap up, and again, really appreciate everyone's participation. Thanks.

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