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[00:00]
[Todd Kuiken]: Alright so basically if you could just start by telling us your name, where you work, currently your role and then describe what you do. And the first question is what did you want to be when you grew up? Or what do you want to be when you grow up?

[Terry Medley]: I'm still deciding. I'm still deciding. Terry Medley and I'm Global Director for Corporate Regulatory Affairs and Advocacy at the DuPont company. I've been in that role [or a similar one] for the last 18 years. Prior to that, I was the administrator of the Animal and bio [Plant] Health Inspection Service at the US Department of Agriculture where I spent 20 years- both advising as well as running regulatory programs. And I was the first director of the USDA biotechnology biologics and environmental [protection] programs. So I've had a long history of both inside the government public service and also in the [private] corporate sector.

[T.K.]: So how did you end up going into this field of study?

[T.M.]: I was—one morning I was asked a question by a deputy undersecretary of the Department of Agriculture, and she said, "What authorities do we have to regulate the products of biotechnology?" I was fascinated by the question. I said, "Well why do you want to regulate it?" And she said, "Well, you tell me."

I spent the next couple of years working with a group of attorneys in Washington that came out with a 1984 document which went through all of our [legal] authorities. And the more I was asked questions about this technology, the more intrigued I became and then I realized that's what I want to do. I want to work in this area in some way and how can I contribute?

That answer came to me after the National Academy of Sciences issued a report which really talked about this technology and we had, the National Institutes of Health was sued because they had allowed—or would have allowed a field trial of a transgenic plant. I just said wait a minute. There must be something that I can do in the midst of this to help this move forward, and that is maybe come up with a way in which we can allow the field testing of transgenic plants. And that was really my first objective was how can we do that? And do it in a safe way one that we could then build upon. So that's how I became involved.

[00:02:35]
[T.K.]: Who would you say influenced your career the most in terms of maybe who—getting you into your first position or even moving from government to industry or within college and

sort of your trajectory in terms what you studied in college, how you got to the Department of Agriculture.

[T.M.]: That's a really long story, but I think it's best if I start with my career at USDA and involvement in biotechnology and there, there was an individual. The administrator, a guy named Donald Houston who was my first boss on the agency side. And he said to me, In Washington it's just as important how you say as to what you say." And that really stuck with me because what I realized—what he was saying is that you should never presuppose that you're right and someone else is wrong. Or rather, look at the other perspectives. Look at the other views.

And so when you translate that into biotechnology in agriculture it was like, what really is the need here from the standpoint of biotechnology and agriculture? Is there a way that agriculture can be helped by this new tool? And that's what I wanted to look at.

I wrote an article very early in my career back in 1989 and that article was about good regulation should ensure safety but also facilitate technology transfer. And that's something that I strongly believe in. It's not an either/or proposition. It's one which you can accomplish both [safely]and doing it in a meaningful way.

[T.K.]: Maybe you could go into a little bit about what you mean by technology transfer. We hear that term a lot, and I think people have different meanings associated with that term.

[T.M.]: Okay, I'll give you probably one of the best examples. I like movies, and there's this movie called *Jaws*. We probably all know about that. You can hear the music now, can't you? Dum, dum, anyway.

[T.K.]: We might put that in.

[T.M.]: Remember that one scene where the regulatory official, the sheriff, sees the shark, and they're in the boat, and he says I think we're going to need a bigger boat? I worked in agriculture. That's where I went after law school, after graduate school. And what I saw in agriculture was agriculture would need a bigger boat. But it would also need a better boat because of all the challenges that we had.

And so that's what I mean by [enabling] technology. Looking at allowing agriculture to have additional tools to accomplish its objectives and missions. And so when I looked at the recombinant technology it was a set of very, very powerful tools that could be used for agriculture. Very, very first [when] this technology was applied it was called the red, white and green [applications]. So we have to help medical which was the red. We had the industrial which was the white, and the green was agriculture. So when you think about this well that was a good thing. The green application. When you think about those three, it's been the green that's been the most controversial. And why?

[cross talk]

[00:06:04]

[Fred Gould]: Yeah, that's what I was going to ask you. Why?

[T.K.]: Why do you think that is, that the agriculture was…?

[T.M.]: Well, when—if we go back to the late 80s and if you asked me then my answer then would be a little bit different than what it is [now] I'm going to give you today's answer. Today's answer is because we're talking about food. And food is very, very personal. When you talk about the health area we're talking about coming up with—we're accustomed to looking at new medicines to try to solve the health problems, and all medicines have side effects. They're a risk that you take, but you're willing to take those risks because of—you don't really have other options. And agriculture especially in the US there are tons of options. We have tons of production. So we're almost at a zero risk base. Why should I take any risk at all if it's unknown?

The other thing is ideology. Ideology in terms of—if you look at production agriculture it isn't the most supported process. You talk about food and we like food to be more local or local production. Not mass. So there were lots of different reasons as to why food and agriculture triggered different concerns than industrial and health. And I think we've been learning that over the last 35 years that it is different. It's very different.

[07:34]

[T.K.]: Do you think there was a point in time when people either forgot or just didn't know—I mean I think people like this idea that they're getting their food or their corn from Farmer Joe down the street but in reality Farmer Joe is really a massive farm and in some instances a corporate owned farm. Do you think there were points in time where there were shifts in the public's understanding or perceptions of how their food is actually produced?

[T.M.]: This is an area where I think there is a lot that's unknown. I think the current numbers are that maybe 2 percent or less of our US population produces all of our food. So when you think about that it's not unusual that people don't know how their food is produced. And I think—so, therefore, I don't believe that one should say the people were not aware. It's just that if you look at the nature of our food supply, it's there 24-7. The options that we have. And so, therefore, the first products of biotechnology were for the growers. And that was another issue. It wasn't for the end consumer. It was for the grower to deal with their pest problem, their weed problems and to increase yield. But as far as the consumer is concerned there really was no difference so why should they take any risk at all? So I think it's something where there has to be a lot—there has been engagement and collaboration to understand these different positions.

[09:24]

[F.G.]: What do you think would be a kind of product that is in the pipeline that would really affect consumers?

[T.M.]: You know that's a really wonderful question because that has been asked for the last two

decades. We've had those discussions. What is it? And you can talk about—so we have the whole area of nutraceuticals and how we could enhance nutrition. But think about it. We had a product like that that's been out there for the past 20 plus years. The golden rice situation. If you look at that in terms of what it was designed to do, to look at vitamin A deficiencies, one would think isn't that the type of product? So I don't really know, Fred, [inaudible 10:10]. So I think we have to look at it maybe in a different light. We have to look at not what type of product would it take to bring that but let's look at what's the risk of not using those technologies.

[00:10:22]

T.K.]: So you've touched on this a bit, but I want to draw it out a little bit more. And it's a broad and basic question but why do you think this technology matters? And what's at stake?

[T.M.]: Oh, okay. It's very easy. I mean if one goes now and you look at our history over the past four decades and you look at yields you will see that there's been tremendous increases per acre. Look at what happened when we went to hybrid seed. So agriculture has a history of where technology has been able to cause major increases to meet production needs. So that happens.

And if you think about it as to why this technology—some of the things we looked at was the ability to maybe look at how nature deals with problems. With recombinant technology, you're now looking at the ability to try to mimic that. Because when you think about things being used if we're looking at Bacillus Thuringiensis, Bt, being used I mean that's just looking at what occurs in nature, right? And how you can deal with it [pest problems].

So I don't believe that we have all the tools that we need. We constantly have to deal with new tools. Look we have weed resistance that occurs. Not with just biotech but traditionally with chemicals and you look at chemicals that have to be discontinued. You look at new pest pressures. So agriculture needs to constantly improve its tool basket to meet its existing challenges.

Now when you look at it in agriculture though in the US, we clearly produce more than we can consume. And a major part of farmer's income today is from the exports. And that's when we look at the current controversies with trade agreements and agriculture says look we need to have these markets. And sometimes 30 to 40 percent of productions are going to be exported.

[00:12:37]

[T.K.]: Maybe you can talk a little bit more about that from your time at USDA and did you guys think about the impact on the farmers in terms of markets outside the US when you were developing the rules around approving or not approving the GM products or crops or what have you?

[T.M.]: But that was happening with other areas. Not just GM. The GM is such a small part when you look at the [oversight of] soybeans or corn. But if you look at other areas we've had huge programs that have been designed to address those [oversight] issues.

So, for instance, one of the things that I worked on when I was at agriculture is I authorized importation of avocados from Mexico. Now you might think well avocados. Now today if you look at avocados they're everywhere. You can go to the Subway. You can get them added on to your salad, sandwiches. You can look at salads. Go back about 20 years and see what was the situation. Avocados were not as widely distributed. They were not readily available and why is that? That's because we had a situation because of plant quarantines we didn't allow avocados in not only from Mexico but from Hawaii. We had California. But we couldn't allow them in.

So one of the things I did was I passed regulation that allowed avocados to come into the—not the 35 northern states. That's where it came in first. And we said we can do this best based on looking at disease pest resistant models etcetera. And we've been able to do that. But again making those kinds of decisions about agriculture allowing things in, realizing that trade is very important to agriculture and if you go back at the US Department of Agriculture whether you starting with NAFTA and coming on forward trade is really important for agriculture.

[00:14:42]

[T.K.]: So this is getting a little more into the details about your career path. So what made you move from government to industry?

[T.M.]: It's really a kind of a—that's really a personal question, but I'll answer it. I was administrator of APHIS, and I was sitting at my desk, and I was reading a letter from a woman out in Arizona. And the letter said, "Administrator Medley I want to thank you for causing the death of my mother. "

Now her mother owned a business that harvests wheat. And this was around the time where we had discovered Karnal Bunt, a pathogen of wheat out in Arizona and part of Texas and a little bit of California. And so, therefore, there was a federal quarantine, but there was also state quarantines that would forbid you bringing the harvesting equipment from state to state. It was actually a state quarantine that stopped her mother's business not the federal quarantine.

But I thought about that, and I'm sitting there, and I looked and said, "Well, I know that the decision I made was the right decision based upon all the data the science, etcetera. Could I have done anything different?" And I looked at—I didn't want to be appear cold and callous but I also I could not appear timid and indecisive in the role that I had. So, therefore, I thought maybe it's time for someone else to sit in the chair, and I had been contacted a year or so about a potential opportunity and I just—I got a call the same day again from the same company. I thought, maybe that's a sign and that's why I left government.

But I enjoyed it—the animal [and] plant [health] inspection service is a wonderful agency to run. I mean it deals with both protecting our plant and animal resources. It deals with things like the psychological well-being of primates; they look at soring Tennessee walking horses. I mean I can go on and on and on. There was—it's a great agency. I had—I

enjoyed it, but I just reached that moment where I felt maybe it's time for me to do something different.

[17:12]
[T.K.]: Was there anything in particular that attracted you to your current position at DuPont versus another opportunity because I'm sure there were many that were presented to you.

[T.M.]: Yeah, it was the fact that I was going to a company that was a science company. I mean you look at the things that they had patented, how they've gone forward with products and it all goes back to looking at science, seeing what is capable, using that for technology innovation moving forward. And they were at that point in time they were thinking of moving into biotechnology and so I had an opportunity to help build that at the company.

[17:49]
[T.K.]: And I'm going to jump around a little bit because that triggered a future question. So I think this may be my personal bias, but I think most people think of DuPont as a purely chemical company, right? Or they see it on their paint cans in their garage. So can you talk a little bit about why DuPont is in the agriculture business and how they came to biotechnology and how they've been innovating since then?

[T.M.]: Well, I think DuPont is a company that was formed in 1802, right? And it was formed by a French chemist who was a friend of Thomas Jefferson. And Thomas Jefferson said to him, look we need a reliable black gun powder for the US to grow. And that's the product that DuPont was based upon. It was black gun powder. A reliable black gun powder. So the history of the company has always been trying to bring innovative solutions to meet emerging needs. And that started with the founding of a company.

[00:18:54]
They've also been a company that has reinvented itself. After every 100 years, the company has reinvented itself. So it started out with gunpowder and explosives. And moved into chemistry and you look at it as better living through chemistry. But then it quickly saw that the next phase when you started looking at the science was really the biological sciences, and that's where the future of the company.

And if you notice last year the company agreed—well, I guess it's earlier this year agreed to a merger with Dow and they're going to merge the two companies and then they're going to form three independent companies. And one of those independent companies is going to be the combined ag which is both seeds and crop protection chemicals. That is really going to be the new DuPont. And then the performance materials is a separate company and then the chemicals that you would think about with Dow. So really I think in about another year we start talking about DuPont you'll be talking about one of the largest ag companies in the world.

[20:19]
[T.K.]: And this might get into some of the controversy I think also as well. But can you talk about how you think mergers like this with large companies and control of seeds or chemicals in this food space that people have a very personal relationship of? Of how that has

influenced or not influenced the debate around GM in agriculture?

[T.M.]: It has clearly influenced debate because part of the debate has been ideology of not wanting large global companies to in fact control food supplies. That's why adoption of new technology is so important.

If you think about it when I was at agriculture [USDA] if you look at the first year of field trials, I think probably 40 percent of the trials were from universities. If you look at the crops that were early field trial, there was a wide array of different crops. Then what you started seeing was a reduction in the diversity of those doing the field trials and then a reduction in the diversity of the field trials. And why is that?

Well, what you looked at—when you start thinking about cost; the cost to recoup, the cost for getting something approved it really needed to be a major commodity. And then to have the resources to go through that approval system; you needed to have resources of [the global] multiple companies. So when you start thinking about it if you really want to control this issue make sure that your regulatory decisions, your policy decisions are good public policy decisions. That they look at both ends of the spectrum of the risks of adoption, the risk of not adopting, and the cost to utilize the tool. I think that with the new world [plant] breeding techniques that are coming along there's supposed to be more efficient, more precise, easier to use. The regulatory policy for those are going to be critical. The OSTP updating [memorandum, I] remember in there one of the problems they point out is we want to make sure that small and medium size companies are able to utilize the technology because that increases innovation and competitiveness. So it's all—it's really all connected.

[00:22:42]
[F.G.]: I'd like to follow up on that. I don't want to get too far off on this merger, but that is a major thing that's going on right now. That they [inaudible 00:22:48] all of these happenings. And this question about small companies and what is the importance of the regulation versus other parts of development of a new transgenic variety?

In the work that we did recently in looking at the cost of regulation compared to development, we had people from certain companies come and say well development the cost of regulation is $150 million. But then when you break it down very little of that cost was the actual tests that were needed to do to get through the regulation, and some of the smaller companies like the apple group told us well, it costs about $3 million to go through regulation. And that the real part was the actual development of a good crop. And that will remain the same.

So a question is even if some of these costs go down, if I'm a small university person and I develop a new trait for corn it's going to have just been somehow licensed to a big company. You're not going to have a lot of small corn companies.

[T.M.]: Yeah, but that's where you're talking about corn but what about if you're now looking at that as it applies to carrots or peas or something else where you could have an impact? The other thing about is I think there's a misperception that there are six or so large

biotech providers. When you start thinking about this area what you have to look at is, go to the American Seed Trade Association; ask them and see how many small seed companies there are. Those are the companies that can really benefit from a newer tool that isn't over regulated. So we want to move away from just the main commodities because those are going to be controlled by large [inaudible 00:24:44]. Corn and soybean and cotton but that's a small part of our food supply when you start thinking of the things on a daily basis. So you said the apple. It's the fruits and vegetables. It's looking at [what]—I want—[what] I enjoy [like] carrots, so I want to make sure that there's improvement.

[25:06]

[F.G.]: Right and it's very interesting because of course, the crops that have been developed are not the things that are going to feed the world directly. Cotton and corn but it's more these smaller crops. And the question becomes are they going to be able to develop these things and move through the regulatory system? And who's going to control that?

[00:25:22]

[T.M.]: And so I think the regulatory and the public policy should and I think that's what the OSTP said you should look at making sure that you do not create barriers to innovation and you also wanna make sure that small and medium-sized companies, as well as academics, are able to utilize the technology for commercialization as well.

[25:49]

[T.K.]: This point might be a little wonky but people might be interested in this, and I don't get to often talk to former regulators. So what is the cost? We always hear about this regulatory cost that is imposed to go through the regulatory system. Do you ever go into detail about what those costs are or where they come from? How that number comes up?

[T.M.]: I'm going to give you two answers on that. And then from those you should be able to complete that picture. The office of management and budget on every major proposed rule there is an economic analysis that you have to do. And you have to say what's going to be the cost of complying with this rule?

When I was at the Department of Agriculture with the APHIS regulations that were published in 1986, our costs analysis said it would cost about a half million dollars to comply with these regulations to move it through, okay? That's a half a million dollars. Today if you go back to what Fred just said on the regulatory costs associated over the period of time to develop the product you're probably looking at anywhere from 8 to12 to 15 million. Depending upon what's the crop, how many tests you do, how many years, etcetera, things like that. That is still very expensive when you're talking about a new crop variety. If you look at the other costs that Fred talked about that, you have to get, that's major. I mean it is major coming up with, and the regulatory cost is just a part of that. But the OMB mandates that as a regulator you specify what the cost of compliance will be. And so it's gone from what was $500,000 [when] we first issued the rule so I think it's probably I'd say it's probably in the $8 to $12 million range now.

[27:43]

[F.G.]: And most people would say that a lot of those costs are not US costs but the cost of regulation from other countries and that's why the apple people said ah, not such a big deal because they were worried about bigger markets.

[T.M.]: Exactly, because you're right. There are other countries that require studies that the US does not.

[28:01]
F.G.]: So what do you think the chances are that we will develop a more uniform approach to this regulation globally that it will move?

[T.M.]: Well, I think that currently—again this is just my own feeling on this. I think that governments realize the potential of new technology from the standpoint of jobs and economic growth. And that they really don't want to close the door too quickly on that. And if you look at what happened with the plant biotechnology that did happen in certain places where they closed the door. Now North Carolina as a state is one of the beneficiaries of that. Because if you look at North Carolina's very early on decided that it was going to create an environment where this technology could be explored safely. And as a result of that most major biotech seed providers have operations in North Carolina. [inaudible 00:29:13

[F.G.]: Were you involved with the North Carolina regulations?

[T.M.]: Yes.

[F.G.]: I was on that same committee. We had the first state law.

[T.M.]: Exactly. The first state law and—

[F.G.]: On regulation biotechnology.

[00:29:31]
[T.M.]: Yeah and it was a state law that said when it's no longer necessary when the federal is enough we'll sunset it.

[F.G.]: Right. Right. And they did.

[T.M.]: But again that was taking a very proactive policy as it relates to this technology and I think that has proven over the years to be very beneficial to the state of North Carolina. Because I don't know of any other state that has the same because they were the first to do it.

[F.G.]: We created the North Carolina biotechnology center which led to that and brought in experts.

[T.M.]: And so that's why I think if you look globally for instance if you think about nanotechnology and the statements that Europe made about nanotechnology in terms of not wanting it to go the same path as biotechnology in agriculture. So I think you see it.

[30:120
[T.K.]: So to jump around but this sticks on DuPont's history. So DuPont obviously has the history in terms of developing chemicals and the risks associated with or clean up

environmental issues around chemicals. Do you—how do you think that's influenced their involvement in some of the newer technologies like genetic engineering?

[T.M.]: Well, I don't. What I will do now is I'll go back to the founding company and if you look at DuPont in the first buildings that are on the Brandywine River there in Delaware they are three-sided buildings. And you might go up and go well, why are they three-sided buildings? And the side that's facing the river is the open side. When you think about their product, it was gunpowder. Gunpowder is very dangerous. There will be explosions. And so the explosions would go out on the water in terms of the impact. And they also adopted a policy that the company would not undertake development of any product that a family member didn't lead. So there's this history, this culture of safety and it's because of the types of products.

So when you're looking at this technology whether it is biotechnology or chemistry, there's always been a strong commitment to product stewardship and safety. And when you look at I guess reinventing itself the company has been moving over the last 20 years into the biological space. Now if you think about the company over 40 percent of its revenue comes from its agriculture units. We have another large section that comes from its industrial biosciences. We have a biomaterials group, Photovoltaic. We also have a large food ingredients company when we bought Danisco so we have a soy [business] that we bought.

So the company has been changing itself but people still think of it as the—but if you look at its earnings, if you look at its revenue and you look at the products it has been moving in that biological space, and this ag biotech was one of the areas that they identified 20 years ago as a growth area to move into for the company's evolution.

[00:32:45]

[T.K.]: So I guess maybe back to the historical context of this. So obviously you've worked both in the government and in industry. Can you talk about some of the important points in that history or milestones either within USDA and within DuPont as it relates to genetic engineering?

[T.M.]: Well, I think Fred mentioned earlier the Organization for Economic Cooperation Development—OECD. OECD is a really important international venue especially when you're talking about the development of new technologies. And they've had there for the past—or since 1983—they've had a group meeting on biotechnology. They've come out with a number of different positions. But what's important about that is you're talking about OECD are the most developed countries of the world. So what's happening there is happening on more of a global perspective, and that's what we really need because as we know, we live in a global society. Our trade it's all global.

And so OECD has been one area that I've been involved in wearing both hats. When I was at the Department of Agriculture I actually chaired the biotech committee at the OECD in joining industry in '98 I became the industry chair of the Business [Industry] Advisory Committee or BIAC which is the official [industry] seat at the table for OECD. And that's

one area that I've found to be extremely useful both for any new technology which we dealt with nanotechnology over the last 11 years. And it's just a very important international forum because these technologies enable technology so we need to look at it with that global eye, not just a US centered eye.

So you're asking about important—the other thing I wanted—there are several others.

[T.K.]: Maybe some dates too if you can remember them too.

[T.M.]: There are several others. I guess the—

[T.K.]: Inflection point in a sense.

[T.M.]: There are several key principles that I always talk about because I think they are foundational to this discussion. And I'll simplify them.

One is the doctrine of familiarity which I'll come back to. Then the substantial equivalency. And then product versus process. And then risk-based mandatory regulations. To me, those are four very critical principles, policies, doctrines, whatever you want to call them that are necessary for emerging technologies.

When you think of familiarity. Familiarity doesn't mean that something is safe. It means you have enough information to judge safety or risk. Substantial equivalency is if you're thinking about whether or not this food is safe. What better way than to compare it with the existing food supply? So is this substantially equivalent? When you think about process versus product at the end of the day are you concerned about how you made it or what's in it? Because that's what you're consuming at the end.

And then when you think about risk base today, especially in the chemicals area, there's a big drive for hazard based regulatory requirements. Is the chemical safe? Well, of course, TSCA was amended for the first time in 36 years this year. And the Frank R. Lautenberg Chemical Safety Act of the 21st Century changes that standard. The standard now under that, is the chemical safe for the intended use?

We know that risk is a two-part equation. It's hazard times exposure equals risk. Risk-based regulations to me require that you look at the total spectrum of the issue. Not just one aspect but oh, this is genetically engineered. Well, yeah, that's the process. But then you want to look at what's the exposure and then look at the risk.

So if you take those four and you keep coming back to them whenever you're approaching a new technology in terms of: is it risk based what we're doing? Is it familiar? Is it the product that we know? And then is it substantially equivalent? And we were discussing substantial equivalent earlier because this whole issue of crop variability. Well, we know naturally there's a lot of variability. So when FDA was looking at it from a food safety perspective they said does it fall within the natural range of variability? If so then that's substantially equivalent.

[00:38:08]

[F.G.]: So related to this and you've been around from the beginning when the whole process in the US was developed a coordinated framework. Do you see—if you were going to do this again what would it look like?

[T.M.]: If I was going to do it based upon new statutory authority—

[F.G.]: Let's try two things. Let's say one due to statutory authorities and due to understanding that we have a Congress and then the other that you were the emperor.

[T.M.]: I don't like the second [choice]. I never do that.

[F.G.]: You know what I'm saying what are the drawbacks having this framework and what could be done to improve it or to replace it?

[T.M.]: You know that's really a question I've had a lot. And it's almost an unfair question because you have to answer it with your statutory authority hat because all the actions were taken based upon the statutory authorities. I mean it was like you have to play the hand you're dealt.

[F.G.]: Let me make sure I have this clear. I thought that the reason it was done within that statutory authority was because the president at the time said no new rules?

[T.M.]: No.

[F.G.]: Oh, okay. That's not—

[T.M.]: No. Congressman—there was Congressman Roe from New Jersey that had the ominous biotechnology bill of 1980. There was plenty of discussions on the hill about new legislation. But at the end of the day going back to my risk base the question was, well if it presents a risk, it's the types of risk that we already have statutory authority to handle. And so, therefore, there's not a need for new regulatory authority.

[F.G.]: Okay, so that wasn't something coming down from the White House?

[T.M.]: No. No.

[F.G.]: I always—I guess I was under the misimpression then.

[00:40:17]

[T.M.]: No.

[F.G.]: I think it's a common belief.

[T.M.]: Okay, no, if you look at the agency statements so for instance APHIS taking the authority that we have and this is—because this is the decision I had to make. If you look at it we

have authority for protecting our plant resources. So looking at plant pests, risks, etcetera. When you looked at the recombinant technology, the question was, well, what's in that technology that triggers this authority? And you and I both know that what's in there is that if you use pathogen—material from a pathogenic source then that's the trigger. And of course the majority of the transformations were being done with a pathogen, and so, therefore, the agency should look at it. Now, of course, we said very clearly we can look at this and determine if you've been able to effectively to disarm the [agrobacterium tumefaciens] TI-plasmid. You can do that. But it was a way of saying we can look at it then hopefully not what you said earlier where we were saying well, we don't have authority. But we can look at it.

[F.G.]: We can.

[T.M.]: We can look at it and then we can say well, yes, you can go forward safely. EPA the same thing with their statutes. I had semi-annual meetings with Canada while we were developing all these. Now Canada has probably—their statutory authority was probably the best suited because remember in Canada it didn't matter which technology you used—old or new if it was a new variety it had to come that way. That wasn't the case here in the US. We didn't have that type of law. But again it's—so I would say that based upon the statutory authority that we—that the decisions were probably the best that could have been made. Based upon the authorities we had at the time. And consistent with risk science-based mandatory regulations.

[00:42:33]
[F.G.]: And how do you see that now as the technology has changed?

[T.M.]: Well, I think what has happened now is it's going to be an addition to the risk. We now are having situations where we are dealing with other needs. So if you look at the new biotech labeling disclosure bill that was passed what that's saying is okay, people we need to have a federal national standard but it is a standard. It's not a mandatory labeling requirement. It is a standard on disclosure of information because people are defining these in different ways. That's needed. Well, the bill was passed for that because the labeling was one thing that had not been addressed to the satisfaction of the general public.

[43:28]
[F.G.]: So what do you see going forward with CRISPR and all these other things in terms of that?

[T.M.]: What I would see there, Fred, is I would hope that it uses the tiered approach that you talked about in your report. So, for instance, the—well, we're talking about CRISPR-cas9 whether we're looking at talens or zinc fingers or other things. I mean there are other things. What you want to do what you've said in the tiered is the first thing is look at the impact of that on the end product.

So if you take CRISPR for instance, you'll have three very different broad buckets that things will fall in. You'll have that very base pair deletion. You'll have a change where you're bringing in something that's capable of being done [through] conventional breeding but you're doing this way you're making it faster, and you'll have things which are transgenic. And you could not have [produced through conventional breeding] depending

on which bucket it falls in that would be what you would need to do. And I'm thinking buckets one and two would probably fall in as equivalent to conventional so therefore it wouldn't have to go forward. Bucket three no, that does meet the definition of a transgenic. It would need to have premarket review. But it just depends. I'm hoping they use a tiered approach to not put everything in the same bucket because as you and I know there are different end applications of that technology.

[00:44:56]]

[T.K.]: Can you think about both of your time at USDA and at DuPont. Were there any—were there any particular people that stand out whether they be—

[cross talk]

[T.M.]: There's a whole—

[T.K.]: What do you remember about working with them?

[T.M.] There's a whole lot. I mean it—and I feel very fortunate that I was in on the ground floor of that discussion. And whether you're talking about people that were in academia like Anne Vidaver or Sue Tolien or whether you're talking about folks that were the pioneers— Mary-Dell Chilton. I know you look at Rita Colwell, look at Roger Beachy, Dennis Gonzales. I mean there are a lot of individuals that—and I won't do justice because I can't remember them all that I learned from.

I also had the opportunity in 1999 to be a part of the EU- US consultant forum of when Norman Borlaug was a member of that. I was one of ten from the US. He was also a member, and I got to work with him over the course of six months on things.

So there are lots of individual that I think have influenced [me]. You talked about some of the people that you had just recently interviewed like Margaret Mellon at the Union for Concerned Scientists. And her colleague Jane Risler].

I mean they were all people that I interacted with on a constant basis getting input on what we were doing and different ways. And so there's a whole long list, and I've benefitted from learning, but I've always been open. I felt when I was at the Department of Agriculture I obviously wanted to hear all the different opinions because I wanted to make the best-informed decision. The operative word being informed. So I talked to a wide cross section [while at the USDA]—at DuPont I've had the freedom to also engage.

So when you think about nanotechnology as a different area but we got together with the environmental defense fund very early to create a Nano risk framework that we adopted for utilization within DuPont. So you know—I think of things globally but I also think of the different positions, and I think everyone has [their views]—you learn from that diversity.

[00:47:26]

[T.K.]: A little different question but it's one that always comes up, and it's about money. So obviously government universities have been investing in agriculture since the beginning but what have you learned about how industry's contribution to agriculture from your work

at DuPont has changed? Or has it changed? How we're developing new agricultural platforms or technologies and whether the balance is correct or not.

[T.M.]: Well I'm not sure I understand the question.

[T.K.]: I guess I'm just asking about over your course of working in this field have you seen the way investment in agriculture has changed? Or has it changed?

[T.M.]: Well, I think it depends upon which area of investment. So for a company like DuPont, there's always—been a long history of a constant reinvesting in research. I mean we've had an entire research complex that's devoted to the acquisition of new knowledge. And if you look at the breakdowns there's a lot of money has been spent on research because it drives the science company to make innovation. I think if you look, the other companies are similar. I mean they have large R&D facilities that they're trying—so there's a constant investment.

But I think what you've seen over the last maybe 10 to 15 years is there are more collaborations between industry and universities. I mean I know, for instance, we had a ten-year program with MIT that was looking at researching in various materials. And I'm sure other large companies had the same thing.

So I think that that's happening more and more and to me, that's a good thing. It's reflective of to meet our challenges today we're going to have to have different solutions that have multiple parties. They're roles that the academic can play. That [industry] can play. That regulators—but it's going to have to really be a collective effort if we want technology to move forward. If we want the public to have ensured confidence and so I'm glad to see that more and more of that is happening.

In my role as head of advocacy, one of the things I've looked at is making sure that I would interact with a very broad cross-section of stakeholders. So again coming back to making the best-informed decision.

[00:49:49]
[F.G.]: That's a very interesting position. Advocacy. Can you describe what that definition is?

[T.M.]: It's basically looking at assuring that those positions that you have, those things that are of concern to you are considered when major regulatory and other decisions are being made. So it's making sure that the DuPont perspective is considered when you're making your decision. And that, of course, leads to lots of different ways that you can do that. But yeah, that's what it's for.

[F.G.]: And do most companies have something like that that they would term that?

[T.M.]: I don't know if it's done the same way. What we did at DuPont was we created a systematic process for effective advocacy that has a number of different steps. And we also created ten corporate advocacy issues across the spectrum that covered food, chemicals, industrial materials and so we kind of did—and I've had—actually I spent 18

months developing that system to utilize.

But I'm sure most people have corporate regulatory affairs, or they have government affairs and those groups do advocacy. But we took a different slant at DuPont. We wanted to have specific regulatory product advocacy, and we wanted to do it in a systematic way, and it's a global responsibility that I have.

[00:51:30]

[T.K.]: So to go back to more general sense of your career path if you could make a graph of your career from when you entered the world of genetic engineering to now, how would you divide it into eras maybe?

[T.M.]: That's really brilliant. I guess I would—the first era would be the—I guess it would be the biotechnology working group and the OECD. So starting in '83 part of my effort domestically was in biotech working group that came out with the coordinated framework of 1984 which most people don't think about today but that particular framework called for a super recombinant advisory committee to look at all of this. And so from '84 to '86 we had a framework which relied upon regulatory agencies. There's a major difference. But so I think that was kind of the first period of what's happening policy-wise here domestically. And then at the same time that was happening globally at the OECD. So I would call the '83 to probably '88 that working group/OECD period. And that's what I was kind of involved in.

The next period was the actual field tests progressing to commercialization period. That was when we had the [1st USDA] regulations; we evolved from field tests to approval processes to commercialization, and that went to probably 1997. And things were really moving.

Then we hit the period which I think probably if I was going to say a low period it happened around the same time that I was leaving the government in '98 because we had a situation. We were getting approvals in Europe the first couple had been approved, and that's when everything kind of hit in terms of the backlash against a particular company and things just changed. '98 I mean things were moving along really nicely and '98 they just changed.

And '98 until now is what I call—I guess it's a period of trying to prevent rejection and then deal with acceptance of the technology. And things like right to know, consumer choice those became issues or the fact of ideology. Do we need this technology? Those are things that have happened since that timeframe.

[54:23]

[T.K.]: Has your perspective on genetic engineering changed over the time or throughout those different eras that you described?

[T.M.]: No. It has expanded. Obviously, there's a lot that you should look and learn as you go forward and that I did. But it didn't change in terms of fundamentally believing that a new technology—enabling technology can be applied safely and it is a benefit. And I see that.

I think that's been justified in terms of if you look at the percentage of our commodity crops the corn and soybeans that are transgenic and then if you look at that on a global basis in terms of the acreage and it has increased every year. And the fact that the number of developing countries actually—I mean if you look at them in terms of the acreage of plant increases are greater than the developed countries.

[55:30]

[T.K.]: So looking back and this may be an impossible question to answer but what do you think was one or a few of the most important contributions that you've made. You've touched on some of them but could you maybe discuss one of them?

[T.M.]: There are two that I'll focus on. The [first] one is very general, and that is the ability to field trial or to field test a transgenic crop. And I say that because remember I said very early on that when you looked at the NIH and the NIH guidelines there was a provision which prohibited the release into the environment of recombinant molecules.

But then what they did is to say is that there can be an exception to that and you could get an exception to do a field trial. That's clearly the release into the environment of recombinant molecules. Well, they were sued. And they were successfully enjoined from allowing that to happen. At that point in time agriculture said, well, I think that we [USDA] can do that. We can set up a regulatory system that will allow this to move from the laboratory to the field. So we can see the next phase. Is this a useful technology? Will it work? And that's what our regulations did that were passed in '87 is they allowed that to happen.

So I think to me that's a major accomplishment because otherwise if you can't move from the laboratory if you have to stay in greenhouses how are you really going to test the technology? So that was one.

The other is the virus resistant papaya. When I was at agriculture, there was only one time that I contacted individuals to see if they would donate technology and it was for the virus resistant papaya. The work that was done at the University of Hawaii that Dennis Gonzales and others left. And this was the story that I was responsible for plant protection. So I had gone to Hawaii. I mean papaya trees are amazing. They can go from a seed to a tree in nine months. I mean it's amazing to see that.

And what you would see is that there in Hawaii there are a number of folks that came from other countries, but that was their livelihood, and they would plant these seeds. These trees would grow and then the virus would hit, and it would wipe it out. It's like well, what are we going to do? That the Hawaiian papaya industry was on its last leg. It was going to be over with. This work that occurred at the University of Hawaii with this technology they came up with the resistant papaya and it saved that industry in Hawaii. And I think that to me was just---that was a highlight. It clearly was a highlight.

[00:58:43]

[T.K.]: So let's—so GM crops obviously come with controversy. Is there a particular debate within genetic engineering that you participated in that you maybe feel most strongly about and

can you talk about what went well in that debate? What surprised you? What didn't go well? How would you do it differently if you could today?

[T.M.]: Well, there's been a lot of them. No, really, there really has been a lot of them. But what I would do is I guess I would go back to my discussion about the OECD. And I can remember when we were at the OECD, the work had just gone into the environment director. At first, the work was in the science director—the director of science and technology [and innovation, DSTI] and was there for probably the first I don't know six, seven, eight years. And then at a certain point the environmental protection agency and USDA we said well, look this is all nice and good, but we're regulatory agencies. And we got to move to the next level, and that is the oversight. And that's when the work started at the environment director.

And there were a couple of things that were really critical. But one of them is the Blue Book. The Blue Book that was produced at the OECD it was a framework for how one could do field testing, release, and the safety considerations. That was pivotal I believe. And global movement on this technology because it wasn't just the US saying this can happen. This was the global community agreeing with the OECD and publishing the Blue Book which laid it out.

And in the Blue Book one of the principles that was very critical was the case by case, and so in Europe, you saw it a lot. Oh, case by case. And that's what the Blue Book talked about but if you read the definition of case by case in the Blue Book what it says is case by case does not mean you can't adopt general rules of applicability that will apply across the spectrum. And those general rules of applicability were really critical in terms of acceptance moving forward with the technology.

[01:01:13]
[T.K.]: So do you have any opponents? Opponents isn't really necessarily the right word.

[T.M.]: I have colleagues who differ.

[T.K.]: Who you really—who you really respect or admire?

[T.M.]: No. [referring to “opponents not the right word”]

[T.K.]: And can you talk about maybe—you don't necessarily have to name them, but if you could that would be great too.

[cross talk]

[T.M.]: I have colleagues who had different positions. And I do say colleagues because when I was both in the government and at DuPont, I was asked about the support that the [special interest] support of scientists would get on an annual basis and I supported that. I felt that they played a very critical role in the evaluation of this technology in agriculture. And that was a group I think if you think about the Center for Food Safety there's been a number of organizations that have had—they were not anti to technology. If you look at the—why am

I drawing a blank on Rebecca Goldburg's organization?

[F.G.]: [inaudible 01:02:36] Weren't you with the Environmental Defense Fund?

[T.M.]: Was Environmental—I thought it was NRDC. That she was with. We'll have to—

[cross talk]

[F.G.]: But anyway she was a scientist.

[T.M.]: Yeah and she was a member of this consultive forum. We talked about issues. Again they had different perspectives, but I respected their perspective because they were, in fact, more science risk-based and what it gave me was additional information to try to make the best decision. And so I think that that was very useful. What the concern I have is where you have groups that from an ideology perspective are saying this—we don't care about safety, we don't need this technology. What am I going to do with that? I mean that's fine, but when you look around at our global challenges, we do need technology. I mean it's very clear. We have population growth. Our aging population. Scarcity in water. There's all kinds of issues that we're facing. And we're going to need help in solving those.

[63:35]
[T.K.]: So to me you have a really fascinating and interesting career path and to maybe get a little deeper into that. So when you were at the agriculture department, you obviously were hearing from both sides. From opponents who were just completely against it. And on the other side from probably companies that were just saying this is going to change the world and there can be nothing wrong with it.

[T.M.]: No actually it was just the opposite. Actually what I had was, and I knew we were kind of at the sweet spot because I had it from both perspectives. One, we're not doing enough. The other—why are you requiring us to do this? This is just like [inaudible 01:04:22], and so that's when I felt maybe we got it right.

[T.K.]: When everyone was angry, right?

[T.M.]: Because when you think about it, it was okay for people to say you're not doing enough. I'll say well; you're doing too much. I mean, that's okay.

[T.K.]: It maybe a different way to ask that so how would you suggest to someone in the public who's hearing about a new technology, how do they cut through all of that noise in order to be able to make an informed decision about a genetically engineered product?

[T.M.]: I don't know if you can. With today's social media and other things, I don't think you can because when I was growing up, I used to—you read. There was the newspaper [which fact checked stories], and there's something about seeing it in writing when you kind of believe it if you see it in writing as opposed to someone telling you. But now everyone's putting it in writing. All the positions are in writing. So if you go well what I want to know about? And you Google it, and you're going to get all those lists of stuff. How do you read

through that if you're just a member of the public saying, "Wow, how do you do that?" And so I don't know with today's technology capabilities will you be able to do that?

And so I think what we have to do is we have to have broader engagement, and you have to have forums for people to understand them. And in this forum the information that comes out of that I can rely upon it because of where it was developed, the safeguards. Again, I'm thinking about the report Fred that you just read. If you look at the academy, I think people still believe that okay, if this report is done by the National Academy of Sciences I should be able to believe in that. And to go forward. And I think that's going to be very useful having those places.

But if you look at—if you develop information in industry no matter how sound, no matter how science based it is, there's going to be a concern. Is it industry funded? Or industry generated? Can I believe it? And what I really think we need is a situation where people have—here are the accepted criteria we're going to use for judging information irrespective of who produces it. And then factual information that we can believe in. And if it doesn't meet this criterion then it's not. So we'll see.

[01:06:53]

[T.K.]: I just have a couple more questions and then if Fred has any.

So this is a broad question. So what do you think has really been driving the field in genetic engineering in agriculture. Maybe you can also talk about that if you can split it up into eras as well.

[T.M.]: What do you mean driven? I'm sorry.

[T.K.]: Meaning in terms of what drove—what's driving the field of genetic engineering in terms of agriculture?

[T.M.]: Oh, well, it's really pretty simple I think. The first generation of products that we've seen that are driving this field. They're driving it because they work. It's pretty basic. The farmer is not going to purchase a product that doesn't work. They're just not. And it was adopted more rapidly than any other technology in agriculture if you look at the record, it was adopted very quickly. And that's because it worked.

Now if you look now though we're in a situation where the acreage might start to be reduced. Now that isn't because the technology isn't good. But it's because the cost that they're now able to get—the cost of the technology and then what they get for their crops. The commodity crops—prices they're getting these days are just—they've been almost cut in half. And so now they're making a business decision. [Can] I afford to buy the more expensive seed under those conditions?

So you've seen actually a small reduction I think as you look at 2015 a small reduction based upon those dynamics and if you look at corn prices today they still are very, very low from where they were. Especially against three years ago. But bottom line the technology is proven, and it works, and you've seen it work over these last 25 plus years.

[01:09:01]
[T.K.]: What do you think are the most important emerging issues related to genetic engineering and if you could maybe compare them to what they were when you started in this field.

[T.M.]: I would say they're probably two or three. The first one that I would say is the issue that's been around for a long time, but it's critical that we resolve it and that's the whole question of low level presence of genetic material when we're talking about global seed issues. And especially when we're talking about it it's not a safety issue it's more of a process issue in terms of it hasn't been approved in this destination country yet. Because we have a sequence of approvals. So you have something that's here in the US. It's approved but it might take another two or three years, and if you have a low-level presence it's like we've seen that happen with shipments of grain. So that's one. Having a global low-level presence tolerance established that everyone agrees with for both seed and feed. That's one. I mean that's really important.

When I look at the other, it is addressing the question that we talked about earlier which is the question of labeling. Now hopefully with the new law and the national standard that will help address that. It will address the tolerance issue, but that's something we're going to have to address as well. So I think probably those are the major ones except looking at of course what might be the mandatory requirements in terms of data submission. Are you going to be able to take advantage of all the knowledge we have from the past 30 years?

[01:11:01]
[T.K.]: So this is I guess a two-part question. Maybe the yin and the yang. So what are your greatest concerns for the future of the technology but also what's your most hopeful scenarios for the technology in the future?

[T.M.]: Well, one of the things—I guess one of my greatest fears is that the technology continues to be held back so that it doesn't fully meet agriculture's needs. So, for instance, having a variety that you're using commercially for eight to ten years—you look at normal agriculture—you have variety of introductory enhancements on a much more frequent basis now. But it's because of the regulatory system that you can't have that type of frequency because [of] what it takes to get it approved, to get it approved in other countries—the markets by the time you do all that and then you look at what happened in Europe you had people pulling products off the market because they said I'm said I'm not going to sell that. That's not a new enough variety now. It's taking too long to get the approval. So that can slow down the technology.

The other is that having the biotechnology or the GMO issue impact the new advanced breeding techniques in a negative way so that the cost associated with using them is such that again people are preempted from using them because of the cost and delays. Because I think that truly has the opportunity to really make a significant contribution to agriculture in many, many ways. Much greater I think than the existing recombinant technology that we're using.

[01:12:52]
[T.K.]: I guess I just have two, maybe three [questions]. How do you feel about the public's level

of trust in government, universities and industry and how do you think that impacts their acceptance, non-acceptance or understanding of genetic engineering?

[T.M.]: Well you know I think--

[T.K.]: And has that changed over the course of your career?

[T.M.]: This is where I probably am a little different on this issue, okay? I think trust is very important and obviously, there's a concern out there in the general public about who can we trust. And whether that's regulators, industry, and even academics. Who can we trust? So I see that. But when I think about this particular issue what I also think about is it's broader than that. So for instance when I talk to my daughter or my son about food we have a lot of conversations about natural clean. If you look at millennials, they have a different way of thinking about their food.

If you go back 30 or 40 years, there was a time when convenience was the driver. You could see it in the marketplace in the frozen TV dinners. Then it became fast, and you had all fast. Then it became buffets, and so we've had these trends. We're now in this trend where it is clearly about clean. You go to universities, and there's a Whole Foods or close to it, so we have to recognize that when you start thinking about agriculture and technology is what do the end consumers want these days?

And so that I think is a little different. I think that's what we have to focus on. It's not making people accept what we're doing. But make sure that what we're doing meets the needs of the individuals. And that's going to be the challenge. But you can't meet those needs without using new technology. And that becomes the conflict you see.

[01:15:10]
[T.K.]: This is may be an impossible question. I don't know if Fred made this question about – I'm gonna blame this one on Fred. But what you like the general public to know about genetically engineered organisms or genetically engineered food?

[T.M.]: What I would—I mean really what I'd want them to know basically is that it's really the same as your other conventional food. I mean really. If you look at the first generation of what we've done in terms of either insect disease, weed resistance and you look at the end product the corn, the soybeans. Now of course with the soybeans, there's a difference if you talk about the high oleic oil. Of course, that's healthier for you. Except it should be improvement. When you think about it really is about assuring that we're able to keep yields sufficient to meet needs. And, but it isn't changing our food supply. But I don't know if you'll be able to do that because of the challenges that we face.

You look at the marketing as it relates to supermarkets and foods. And you go anywhere now, and there's a huge increase in the organic sections. And when you think about—if you think about food safety I'd say food safety, I can tell you that transgenic corn has a less likelihood of being hit with a fungal mycotoxin than conventionally bred corn. But does that really mean anything to you? If I tell you that with this technology, I can create soybean oil which is closer to olive oil when you look at the oil's contents. Does that mean

anything to you? It's how do you get people to want to relate to believe that when most things you see—even where there isn't any GMO it's no GMO. I mean that is so common on so many food packages now and why?

[cross talk]

[Karina Todd]: It also says gluten free.

[T.M.]: Yes. That is and so—

[F.G.]: It's like when you buy gummy bears, and they say that they're fat-free. Well, they're only sugar. So to just take this for a second we had a meeting here on co-existence.

[T.M.]: Oh, I'm sorry. That was the other issue. Thank you, Fred. If we even know that. I had that in my head. Remember I said there were three things? But it's—that's a huge issue. It's coexistence and cultivation okay? Because if you look at what's happening in Europe, the approvals have been for food and feed, not for cultivation. And so if you look at coexistence, if you're not planting how can you really deal with it? So that's an emerging issue. Is cultivation and yeah. Coexistence.

[01:18:27

[T.K.]: Can you describe that a little bit? There might be some people who don't know those two concepts necessarily.

[T.M.]: Which ones?

[T.K.]: The coexistence and cultivation.

[T.M.]: The thing about it is if you think about planting crops and you want people to have choice, right? So you can have choice. And you want to have a situation where, can conventional, and transgenic crops coexist? And if so, how do you do that? Because you have a lot of concern about there's cross-pollination and I won't say contamination when people talk. But cross-pollination and what that might mean. So I think I know that the sector of agriculture's AC 21 group is looking at this whole issue of coexistence. So that's key. The other is cultivation and what's happening there it's really—there are a number of jurisdictions which are trying to have cultivation—

(PART 2 OF INTERVIEW AUDIO)

[01:20:03]

[T.M.]: …bans which say you cannot plant a GM crop. If you think of what happened in Europe. In Europe, they finally said okay, a country can decide to ban its cultivation for other reasons. And that was looked upon as a victory because it meant those countries that wanted to have cultivation can now have it. Whereas before cultivation was banned across. So if you look at coexistence as really critical and how do we do that? And then making sure that we don't have an increase in cultivation bans which says you cannot plant GM crops.

[F.G.]: So just to pick up on that, that's perfect then. Because when I first heard of coexisting oh,

yeah we coexist whatever. I didn't know what that really meant either. So but to go back to that when we had this meeting it was out of the AC21 [inaudible 00:00:56] where they couldn't come to a conclusion and Secretary Vilsack wanted to push it. And he came here along with all the other groups. I mean we had a very diverse group there.

But what surprised me he was very effective in the beginning. He gave the introductory talk, and he said, "I don't want to talk about science. I want to talk about having a vital agricultural economy", and it made me think. What he was saying was well if you go to the store and you have an array of cereals whatever—everybody is free in a democracy to choose whatever cereal they want. And they can believe crazy things, or this is good, or that is good and he was saying, "Look, there are people who like organic and its growing sector in the economy if that's leading to a profitable agriculture in coexistence with the other kind of agriculture, let's come up with a way to make it work." And it didn't work out quite that way in the meeting because everybody was still talking about that. What do you think about that?

[T.M.]: Well going back to one of the things I said earlier with the low-level presence issue for coexistence I think one of the key fundamental pillars is going to have to be a tolerance for some level and some minimum threshold level. If you can agree upon that then I think you're able—you can best deal with that. But if you have a situation where you find anything that's going to just constantly feed conflict.

[01:21:54]]

[F.G.]: Right. So I think that's a good technical point but what you brought up before about the millennials and how they think of—what do you think of Vilsack's perspective on this that look it's just another way of marketing and let's try to have it. Is that good or bad? I mean is that true?

[T.M.]: Oh you mean to try to have the coexistence?

[F.G.]: Allow coexistence just so we can have a market so you could have Cheerios and you can have Corn Flakes.

[T.M.]: Well, yeah, I mean that to me that's really the ultimate consumer choice. I think what's happened over the last several years on the whole labeling issue, there was a discussion about well, why don't you want me to know? That was never the issue. Or I have a right to choose. That was never the issue. The issue was labeling that would be used to say this product is unsafe. That would be false and misleading. That was the issue. And that's why—or to say because of this technology and because of safety it requires premarket approval or labeling when there's no basis for it. So that was the issue here.

But again in terms of allowing people to choose there's been total support for that in consumer choice. I mean we sell both varieties. We sell genetic; we sell provisionally bred seed. Yeah, you meet your customer's needs.

[01:23:24]

[F.G.]: That's an interesting kind of thing just for a minute. A scientific perspective is the same

thing like with the gluten free or the fat-free. Customers are buying something that they think is more healthy or more natural for them but it's not. But yet that's their problem or whatever. If you buy gummy bears because they're fat-free who am I to tell you, you can't. But there are some things that don't feel quite right.

[T.M.]: But you see when you take that you then go to the next step and you say, okay in addition to this labeling we now want to have cultivation bans that were being discussed in states and counties. That's—it's more—it's where oh, we want to have a symbol like a skull and crossbones. There're things that that's definitely misleading. So FDA has always said you can have labeling but the labeling cannot be discriminatory. It cannot be false and misleading. And it has to be truthful. And it wasn't meeting all standards.

01:24:26]

[F.G.] Do you have more questions?

[T.K.]: The only—the last question we always ask is there any questions that you thought we were going to ask that we didn't or basically it's to give you an opportunity for you to basically leave us with any final parting thoughts.

[T.M.]: Yeah, the one question that we didn't talk a lot about and I don't think people ever do that. And I like to talk about it, and that is if you're thinking about the technology you're trying to address the risk. And that's been a lot of discussion early was the risk associated with the technology.

To me to be able to really do that you also have to look at what are the risks of not utilizing the technology? I go way back to I think it was Aristotle that talked about the difference between a theoretical and a practical science. One being the acquisition of knowledge the other being the utilization. And so utilization is really important.

And so when you think about these what are we losing if you don't have the technology, don't use the technology? If you look back over the past decade, one could probably come up from a carbon utilization perspective in terms of fossil fuels. Use reduction based on newer technology. Is that useful when we're talking about addressing climate change?

So again look at the whole picture, not just one aspect is what I would say. The answer might still be the same. That's okay. But make sure it is a comprehensive look. That's the [end goal].

Interviewer: All right. Thank you so much for doing this. We do have—

[end of audio]
[01:26:29]