

## MODULE IV

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### REGULATION, CONSUMER ACCEPTANCE, AND RISK MANAGEMENT

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## *Panel Discussion and Q&A*

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*Thomas Hoban:* It's fun for me to come back here and talk to you again. I've been on a number of NABC programs over the years and have had some of the papers published. I am back this time as a disinterested observer because I'm really not involved in biotech much anymore. I've moved on to bigger and better things.

So, let me reflect on some of the issues I see coming along. First of all, I'll give you a few main points. The major issue is that this is about food, it isn't about farms. Food is a very emotional and ethical subject for most people. People react with their guts, they don't react with their minds. This is not about sound science, again this is about ethics, confidence and trust. The second main point is that American arrogance and aggression in this area—as in many other areas—has alienated most other countries. We're now seen as using poor countries as pawns. We have no standing with the world when it comes to food because we are seen as barbarians when it comes to our own food lifestyles, certainly relative to Europe. So the European Union, with their cautious approach, is winning the hearts and minds of many other parts of the world right now because by contrast we look pretty callous. Again, this is all about confidence and trust. The data are in. I've seen some of it. People no longer trust the government in the United States. It's clear that people especially fear large corporations. I've been teaching a lot with under-30-year-olds. Young people are convinced that the most serious threats to their lifestyles and to their future are large corporations. They are not afraid of NGOs and things.

Another important consideration is that, regardless of what scientists and technologists say, organic food has become the gold standard against which everything else is judged. And much of their market appeal is that they can put right on the bag—even though FDA was supposed to write rules about this but didn't—"non-GMO." "Buy this product,

spend the extra dollar, because it doesn't have GMOs in it." That's what we are seeing. I hope you all paid a lot of attention to Mark Nelson from the Grocery Manufacturers of America (GMA), because the big food companies have all bought organic lines. Kraft owns Boca. General Mills has Cascadia Farms. Kellogg's has Morning Star Farms. On and on. They are going to play both sides of the aisle and they are ready to turn their businesses around and aim in that direction as they see the market develop.

And as a sociologist, this is an interesting example of what we call cultural lag. And this is where the material culture, the science, the technology, is far outpacing our nonmaterial culture. I'd say we don't have the knowledge, the attitudes, the regulatory or policy systems in place to deal with these technologies, and we're only talking about plants. The big challenges are going to be in human genomics, human genetics, and NABC just sticks its head in the ground when it doesn't even look at those issues. The fact that you've excluded animals from this discussion is really interesting because that's the one that's going to blow up in everybody's face.

Let me get a little more specific. I've looked at a very good study from Rutgers. I had a chance to review all the Council for Biotechnology Information tracking data, which I'm not going to talk about in detail, but there are some real clear trends in the United States. One of the most disturbing things is that the vast majority of people in the US still don't have a clue that products in the supermarket contain genetically engineered ingredients. They are still saying, "Oh no, I don't eat that." It's still a common fallacy. And as people find out, they are finding out because they are learning about the negative side. They're not learning about it in any positive way. And, increasingly, the data that aren't usually shared show that there is increasing concern over risk among US consumers. And that has increased over time. The food industry itself—in terms of the state of social acceptance—is about to pull the plug. You need to pay close attention to what GMA says about PMPs. And you aren't even listening to the food retailers and the restaurant chains because all they've done is told the manufacturers, "Keep that junk out of our food." You know the whole system is blocked at that end and there's no sign that anything is going to come along that's going to spring that open. A food retailer will still be very, very susceptible. And the bottom line, as I think we are finding, is there are no benefits for any of these stakeholders, including consumers. There is a perception of possible risk and so, in many ways, it's very rational to reject the technology. With Europe, the interesting thing there is the data showed that things were actually looking a little better, then along came the WTO lawsuit to the front page of the paper, and the Europeans dug in deeper than in the past.

Where would I lay the blame for all this? I would lay it at the step of the Bush administration. The main indicator of that is they never bothered appointing a full-time FDA commissioner. It was just not important enough. We've got Les Crawford in there, nice man, strong industry advocate, strong lobbyist for industry, but they never bothered getting a confirmation on a full-time FDA commissioner. That just shows you where the priorities are. The WTO case was brought 2 weeks after the misplaced Iraq invasion that we are still trying to dig out from under. And the headlines in the European press were in terms of retaliation against the French for not backing us in Iraq. One thing I did

support: towards the end of the Clinton/Gore administration, FDA hearings were held on the future of food and regulations. The one thing that everybody agreed on, from Greenpeace to BIO to everybody in the middle, was that there ought to be mandatory premarket notification of FDA. Well, Les Crawford, in his great style, said, “You know, we don’t really need to do that because we can trust all the companies. They’re going to come in to us voluntarily.” And that shows you the mindset of the administration.

As I mentioned, there were supposed to be labels that would prevent misleading promotion of products as being “non-GMO”: but, we never did it. The one that is going to come back and hit the hardest, though, is this continual push to try to convince people that meat and milk from cloned animals is substantially equivalent. The public knows that is not true. The scientists can’t even say it’s true. Everybody knows it took 300 mistakes to make Dolly and then she died early. Nobody wants to eat meat or milk from such animals. What I’ve seen is just pretty much characteristic of this administration: the wrong decisions at the wrong time at every possible opportunity.

Finally, how about a few implications for the universities? I think there is still a lot that we can do. What this industry sorely needs is something that people may actually want, something that food consumers may actually demand. If you go back to some of the horticultural crops and produce, some of the flavor-saver constructs, and deliver something to the consumers that they actually like, you might even make supermarkets receptive. I think universities need to quit being so hung up on sound science. There are many, many other ways of knowing. And when it comes to food there are many, many other things that are much more important to people than sound science.

I’ve published a review of a film made by Deborah Garcia, *The Future of Food*. It’s an unabashed attack. She’s likening herself to Michael Moore. It summarizes all the concerns that people have, and I think that’s one of the things that universities need to do more of. You need to start inviting and engaging the critics. You need to listen to someone else besides the biotech industry. And I know—coming from a land grant university—that the people with the money, it’s tempting to listen to them. But I really think that we need to do a much better job as universities of being honest brokers and asking the tough questions and coming up with answers that may or may not be politically correct.

*Canice Nolan (European Commission to the United States, Washington, DC):* My mission is not to convert you to the European ideal. My objectives here in the United States are to listen, to inform and to promote the dialog. In the area of GM, dialog is something that has been missing for several years, mainly due to the fact that a WTO case is going on and our instruction in the past has always been, “When there is a court case going on, you speak through the lawyers, you don’t actually speak to the other parties.” This is important. Before coming here, I was responsible for six years for pesticide legislation in Europe. As a scientist, I learned very quickly that you don’t play political games. You don’t play with journalists because they are professionals and they will eat you alive. I’m a scientist and I prefer to stick to the science. I learned how valuable that was in the area of pesticides, because there are many people who don’t care what the risk assessment is, they just want it banned anyway. I heard reference to “zero zealots” this morning. I’ve also

heard these people referred to as the taliban: “tali ban this and ban that and ban the other,” and it doesn’t matter what’s out there. Now, with respect to GMOs, you have to see it in the larger context. We had food scares in Europe, mad cows, dioxins and so on in the 90s, which threw the whole food supply system into doubt. At the end of the 90s there was a period of reflection that included GM. During that time we set up the European Food Safety Authority. We brought in a huge amount of new legislation on food safety. Also in the area of GM we brought in new rules, new scientific requirements, scientific assessments, rules on labeling, on traceability, and things had started moving again in the sense that requests were moving through the system. We had a new commission at the end of last year, and one of their first actions was to stop and say, “Well, GM: yes the commission is pushing it. We’ve analyzed case by case, we’ve seen where things are safe, we will go ahead and make positive proposals.” But the member states are still not on board. So, there was a period of reflection in February, 2005, in the commission and it was agreed that the system we have in place is a good, correct system, so let’s continue with it as is. And we have continued pushing forward proposals. You might say everything is okay now, everything is moving; well, in fact, everything is not okay. Everything is *not* moving as we would like and there are a few reasons for this. One of them is that the real problem is not with the regulators, the problem is with consumers. And the politicians see that consumers don’t want this. The supermarkets see that the consumers don’t want this. And they’re not buying; they’re not sourcing. The food processors are not sourcing where there is a risk of GM and, until the consumers are convinced, I’m not sure that the markets will allow GM to go forward in Europe. It doesn’t matter what we as regulators say. It’s the market that will rule the game. And the politicians are just being responsive to the wishes, if you like, of the electorate. The GMO case is almost seen as big industry forcing unwanted food down people’s throats and the commission sees itself almost in a position of being a tool of industry in forcing this down people’s throats because the laws say that it is safe that you have to put it out there. I’d always thought that the American system was that the consumer is king and what the consumer wants the consumer should get and if the consumer doesn’t like this, well the consumer doesn’t have to have it. In the field of GM, I have the impression of the industry saying this is good, take it, buy it, eat it, it’ll do you good, and we have to get around that disconnect if we are going to make progress in this area.

*Allan Bennett (University of California, Davis, CA):* One of the themes that has gone through this meeting is the opportunity for a greater diversity of agbiotech products. Also a notion that was mentioned by Roger Beachy has come up again: the opportunity for new players, including the public sector, as developers and providers of new GE crops. A few of us believe that the markets would react differently today if, in fact, there were additional players in this field and additional products representing broader diversity. Clearly, some high barriers are working against this objective of diversity of products and of players. The irrationalized regulatory environment and its smothering effect on development and deployment of new phyto-technologies has been addressed over and over at this meeting. The bad news that I want to present today is that you also need to

navigate a thicket of patents before you can even get to these regulatory hurdles. So, my role is to shine a little bit of light on the intellectual property environment that is also impacting what projects can advance and what institutions can effectively move along the path to product development.

Interestingly, these two areas—intellectual property and regulatory approvals—are not unrelated. The regulatory environment imposes high cost on the ultimate deployment of a product and, in industries where there are high regulatory hurdles, intellectual property becomes extremely important simply because no one is prepared, or willing, to invest the cost required for regulatory approval unless they have exclusivity to market the product. And so, in this sense, intellectual property is very important in fueling innovation and it is very important fueling innovation in this sector. Having said that, intellectual property—if the landscape becomes too complex—can also inhibit innovation, and that’s the situation that we are dealing with here; it’s clearly important, but has developed into a complex landscape. So, what does this intellectual property landscape look like? We’ve studied it a little bit. It turns out there are sixteen to twenty thousand patents in the crop biotechnology sector, depending on what and how you count. That’s an interesting number given the very narrow base of products that we have in this arena. It’s clearly not for lack of innovation and innovative technologies that have been developed. These cover the so-called enabling technologies such as transformation methods, selectable markers and promoters. In an ideal world these enabling technologies would be very broadly available, licensed on a non-exclusive basis to enable a wide diversity of players but—unlike medical biotechnology, where in fact that did occur—it didn’t happen in agbiotech. Therefore, many of the enabling technologies are very narrowly owned and strategically deployed rather than supporting broad innovation. There is an initiative called BIOS, Biological Innovation for an Open Society, in Australia, which is attempting to invent new enabling technologies and make them broadly available free of charge. This group of sixteen to twenty-odd thousand patents also covers the trait technologies—genes that encode specific pharmaceutical proteins or traits such as disease resistance, which is the arena in which exclusive access is critically important. Elizabeth Hood indicated that somewhere in the neighborhood of seventy-five licenses were needed to encompass all of the technologies for the production of trypsin, very similar to the seventy-odd technologies required in the production of golden rice.

To address some of these issues, twenty-eight universities and not-for-profit research centers have joined forces to create the Public Intellectual Property Resource for Agriculture (PIPRA). In this area, there is strength in numbers. Fully 25% of crop-biotech patents represent inventions that were made in the public sector, and this is about a 10-fold higher proportion than in any other technology sector. So PIPRA, as a collective organization, represents a very broad and significant portfolio of intellectual property. What is it doing? It’s deploying a unified database of all the public-sector intellectual property, helping organizations and individual researchers evaluate freedom to operate around specific technologies, developing transformation vectors that have maximum freedom to operate and it’s working towards a collective management—bundles of intellectual property for multiple institutions—to try to reduce these transaction costs. PIPRA has

a vision and this vision is related to something we heard yesterday: to be able to partner with an organization such as the Specialty Crops Regulatory Initiative (SCRI), and jointly navigate both the intellectual property and the regulatory environments that will deliver the benefits of biotechnology to a broader base of crops and to consumers.

*Bruce Ferguson (Edenspace, Chantilly, VA):* My first question is for Tom Redick. Given this evolving standard of strict liability now that is being faced by seed producers and sellers and others in the agricultural chain, has any effect been observed yet on insurance rates or availability of insurance? Private insurance?

*Tom Redick:* This is a rapidly evolving situation. Domestically we've had troublesome memoranda from our main brokers who appear to be having lunch with activists in their spare time, talking about how these risks are so great, and that we need to discontinue coverage on various aspects of production. And these insurers will actually pull all of my growers' pearls, just in the name of biotech. They did the same thing with mold coverage. They said because of mold problems we're not covering any losses from water damage. So the insurance industry is reacting. What we've done on the growers side is we've calmed them down, domestically. Internationally there's a company called Swiss Re. It's a big re-insurer and they're a big troublemaker. I think they're having lunch with activists too and they sent an entire CD of material of what I would call inflammatory presentations to the biosafety meeting and handed it out and didn't consult with industry in advance. So I do think there's an insurance that's available and, as I noted, physical injury has been recognized by the courts, from commingling, and that goes right into the basic standard insurance policy and gives coverage. That's why, when the insurers tried to take it away, we really complained quite bitterly and said, "You already cover this and you're not going to take it away." But yeah, it's something I'd love to see, frankly, more Europeans getting involved and just maintaining the level of insurance coverage that already exists so that they don't pull it away. I think the activist goal is: eliminate all insurance and you eliminate the industry.

*Ferguson:* A quick follow up question for Cindy. Has there been any contingency planning or other activity looking at how the existing framework of government agriculture insurance might be supplemented or extended to backstop farmers and others in this industry in the event that private insurance becomes much more expensive or unavailable?

*Cindy Smith:* I want to make sure I captured your question. The question is: is the government, from a regulatory perspective, looking at the question of liability insurance?

*Audience Member:* My understanding is there is a pretty broad framework of crop-support insurance for instance for farmers, but I'm not certain, I haven't looked at whether it applies to farmers who have economic harm from inadvertently having a little bit of DNA in crops sold to Europe. I see some headshake no, so I'm assuming that perhaps it doesn't extend that broadly. I come from another industry where the government did

step in to provide liability backstop and I don't think it's a really directly comparable industry—the space launch industry—except to the extent that there were some hazards in commercial space launches that were very low risk yet could not be insured because they were so hard to calculate. The example often given was a commercial rocket landing on New York City; very low probability but hard to insure against. So, just as a reference, the government has stepped in—both in that and the nuclear power industry—to provide some creative frameworks for liability protection, for the participants in the industry. I just wondered if your office, or anybody else in the USDA, is looking at that whole area as another means of encouraging innovation in this sector?

*Smith:* This is a little separate from my area, but relevant for other parts of USDA. Probably what I can offer most relevant to the question is what we've done. We've had some of this kind of dialog at USDA as compliance issues have arisen, particularly with the ProdiGene issue. At the time, we were questioning their ability to assume the loss that was going to be associated with their lack of compliance, and made a decision, which was later criticized, to have the department put up the initial money to ensure that the company could eventually directly assume the loss rather than have that loss spill over to farmers or others. So, the way we have addressed this to date has been to look at each individual situation and, with respect to what we've been regulating, and make every effort to hold the company directly accountable for lack of compliance. We've had some other situations too. Fortunately we've had a lot of success in getting companies to agree to address those issues. But clearly there's a larger question here that is probably a whole other discussion that should be considered and include other parts of USDA and the insurance industry.

*Henry Miller (Hoover Institution, Stanford, CA):* One concept that is dramatically under-represented here is that the universe of recombinant DNA-modified organisms, whether you call them GMOs or GEOs or GEMs, is not a meaningful scientific category. It's not amenable to generalizations about risk or safety and, if you doubt that, look at the lists of topics at the Keystone meetings and the Gordon conferences and they don't focus on recombinant enzymology or recombinant bioenergetics. That has important implications because regulators like Cindy Smith saying that her agency has a scientific approach and it's dedicated to science, doesn't make it so. You labor within an irrational scope of what comes in overall to your system. And in science you don't get to be scientific for just a little bit of the process. You have a process, as does EPA, where the degree of government scrutiny is *inversely* proportional to the degree of risk. You are regulating a superior technology more stringently. And you are very congenial and you are very collegial but it doesn't make your scheme any more rational and it doesn't make the obstacles that you put in the path of research in industry and in academia any less.