

UNITED STATES DEPARTMENT OF AGRICULTURE

In the Matter of:)
)
STAKEHOLDERS MEETING)
MEETING WITH NORTH AMERICAN)
MILLERS' ASSOCIATION)

Training Room 1
4700 River Road
Riverdale, Maryland

Friday,
March 12, 2004

The hearing in the above-entitled matter was convened, pursuant to Notice, at 9:11 a.m.

BEFORE: CINDY SMITH
Deputy Administrator, BRS

APPEARANCES:

On Behalf of USDA/APHIS/BRS:

John Turner
Neil Hoffman
Chris Zakarka
Sally McCammon
Susan Koehler
Michael Wach
Lee Handley
Virgil Meier
Terri Dunahay
Subhash Gupta
Michael Watson

On Behalf of North American Millers' Association:

James A. Blair, Vice President

P R O C E E D I N G S

(9:11 a.m.)

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MS. SMITH: Good morning and welcome, Jim.
Welcome to our state quarters discussion series on our
upcoming EIS and our revised plant biotech regulation.

We want to thank you for taking time, I know your
schedule is busy, to participate in this meeting and share
your thoughts with us.

Primarily we have two purposes for these briefings
or these discussions that we're having. The first is to
give us an opportunity to share information about our plans
to move forward on the EIS as well as our plans to move
forward on the rising of biotech rights and then the second
is to give us an opportunity to gather a diverse and
informative input which will support and effect the decision
making on our part in revising our regulations.

We have here from BRS part of our management team,
as well as additional members of our staff. When available,
we have other Agency personnel who are supporting this
initiative so they may come and go from meetings as well.

I do want to point out two key individuals who
have now been dedicated to providing full-time management
for our work and developing the EIS and the plant
biotechnology rights so you have contact people to have
further discussions with.

1 The first who you likely know is John Turner.
2 John's a very important member of our leadership team here
3 at BRS and I'm very please to say that John is leading this
4 on a full-time basis in terms of management of both the EIS
5 and the development of the new plant rights.

6 And a second individual which is a new face you
7 are not likely to be familiar with is Dr. Michael Wach, a
8 recent BRS hire as an environmental protection specialist
9 within our environmental ecological analysis unit, which
10 Dr. Susan Koehler heads up.

11 In addition to possession a PhD and an
12 environmental law JD, Michael brings research experience in
13 plant pathology and weed science, as well as legal
14 experience working on cases involving the Clean Water Act,
15 the Clean Air Act and other environmental laws.

16 What I'm going to do at this point is hand it over
17 to John Turner to provide some additional information about
18 our plans for this meeting and then after he provides that
19 brief information to you, we're just going to open it up to
20 however you want to use the time.

21 You've already said your intention is not to read
22 a statement, but we can just have whatever kind of
23 give-and-take clarifying information or discussing some of
24 the issues as you would like to.

25 MR. BLAIR: Okay.

1 MS. SMITH: John?

2 MR. TURNER: Thanks. As you may know, we recently
3 participated in inter-Agency discussions with EPA, FDA and
4 the White House, which concluded that the coordinated
5 framework has provided us an appropriate science and risk
6 based regulatory approach for biotechnology, but still it
7 recognized that the Plant Protection Act of 2000 provides a
8 unique opportunity for APHIS to revise its regulations and
9 potentially expand our scope, while leveraging the
10 experience gained through the years through our history of
11 regulation and using the Plant Protection Act, we might
12 enhance our regulatory framework and might be well
13 positioned for future advancements of the technology.

14 We also included those discussions with some
15 general agreement on how the biotech regulatory approach
16 should evolve, but still there's much opportunity for public
17 and stakeholder input on how the regulatory approach will
18 evolve.

19 So given this, what we would like to do in these
20 meetings is hear your thoughts, as well as have an informal
21 give and take of ideas and it's a unique opportunity for
22 this type of discussion, because we've not yet begun the
23 formal rule making stage.

24 So, we're free to speak openly and exchange ideas
25 with stakeholders in the public. You'll notice that our

1 discussions are being transcribed. This is for two reasons.

2 First, we want an accurate record of our discussions to
3 facilitate our ability to capture and refer to your input.
4 Secondly, in the interest of transparency and fairness to
5 all stakeholders, we will be making available as part of the
6 public record and potentially on our website documentation
7 of all the stakeholder discussions so that the public and
8 the other stakeholders will all have the benefit of the
9 discussions that we're conducting.

10 Of course I should emphasize that while we will be
11 happy to share information on the direction we would be
12 likely to be taking during the process, certainly the input
13 from public and stakeholders will influence our thinking as
14 we go forward.

15 In addition, officials within USDA, such as our
16 Administrator, the Under Secretary, the Office of General
17 Counsel and the Secretary will be expected to provide
18 insightful direction as well.

19 While we value all input, it is important for us
20 to recognize that our thinking will likely evolve and while
21 we may have some enthusiastic discussions on a particular
22 aspect of our regulation revisions, it will be an evolving
23 process.

24 Finally, since it is hard to predict what the
25 final regulations would look like, what we can share is our

1 BRS priority areas of emphasis, because we know that these
2 are going to help set direction.

3 The first is rigorous regulation, which thoroughly
4 and appropriately evaluates and ensures safety and is
5 supported by strong compliance and enforcement.

6 The second is transparency of the regulatory
7 process and decision making to stakeholders and the public.

8 This is critical for public confidence.

9 The third is a scientific based system, ensuring
10 the best science is used to support regulatory decision
11 making to assure safety.

12 The fourth is communication, coordination and
13 collaboration, the full range of stakeholders.

14 Finally, internal leadership, ensuring that
15 international biotech standards are science based, as are
16 ours, supporting international regulatory capacity building
17 and considering the international implications of policy and
18 regulatory decision.

19 So as we begin our discussions, I would ask you
20 just you have a mike on your table, to speak near the mike.

21 The first time you speak, if you would just say your name
22 for the record and with that, I'm happy to open up the
23 discussion.

24 MR. BLAIR: I am Jim Bair. I'm Vice-President of
25 the North American Millers' Association here in Washington,

1 D.C..

2 Let me start by saying that I want to compliment
3 APHIS for this activity. I know this represents a
4 tremendous body of work and it's, I would say in my 15 years
5 of being involved in regulations and regulation development,
6 that it's unprecedented in my experience to see this sort of
7 effort and I think APHIS is to be complimented for it.

8 I think after I give some context to my remarks in
9 a moment, I will say that I think that this communication
10 element is in the public eye, is as every bit as important
11 as the science element and I'll come back to that in a few
12 moments.

13 Let me start by offering some context, which may
14 help you understand whatever remarks that I make during our
15 discussion. Let me first start by telling you about the
16 North American Millers' Association.

17 We are the dry processing industry in the grain
18 processing segment. We represent 45 companies that operate
19 175 mills in 38 states and they collectively produce more
20 than 160 million pounds of wheat, corn and oat products each
21 and every day and that's more than 95 percent of the U.S.
22 milling capacity.

23 What do we do? Very basically, we grind and sift.
24 We don't change the nature of grain tremendously. Our
25 customers may, but we're not a wet process that's using

1 solvents and extracting and so forth. We grind and sift the
2 grain into its various constituent products and that would
3 be either wheat flour, corn flour, corn grits, cornmeal, oat
4 flour and so on and so forth.

5 So this would be servicing the very widest range
6 of grain-based food products. Everything from bread and
7 cakes and crackers and cookies from as wheat products to in
8 the corn grinding business, brewers adjuncts, cornmeal for
9 cereals and snack foods, oats of course breakfast cereals
10 and others.

11 We're the last segment of the vertical grain
12 industry that sees it as raw grain. When it leaves our
13 mills, it's no longer grain. It's a processed or
14 semi-processed product.

15 We have therefore the responsibility of making
16 sure that whatever grain enters the food supply is safe and
17 wholesome and it's a job that we take very seriously.

18 Our industry has, over the last two years, we've
19 closed about ten percent of our industry capacity over the
20 last two years. In 1900, the flour milling industry was the
21 largest industry in the United States and while we are not
22 dot com or high tech, in fact we're probably 180 degrees
23 from dot com and high tech, but we're a mature business.

24 The reason that I share that is to say we have
25 developed over the decades in the United States brand

1 loyalty, brand allegiance to our products. Customers have
2 assumptions about the safety and wholesomeness of our
3 products and it's again something that we take very
4 seriously.

5 We already find ourselves under attack by things.
6 Atkins and other fad diets and other influences which we're
7 struggling to understand. So when we already feel like our
8 industry is somewhat under attack, that makes us perhaps
9 hypersensitive to other risks.

10 As I have explained to some of you in the room
11 previously, we're perfectly capable of messing things up on
12 our own, but when either another industry or uninformed
13 regulators or other groups over which we have no control add
14 risk to our business, that makes us understandably upset.

15 As the last link in the chain that sees grain as
16 grain, as I said, we're responsible to our customers and our
17 customers are the manufacturers of the grain and food
18 products that you see in your grocery store shelves and they
19 are likewise hypersensitive to any risk of product recall,
20 brand degradation, loss of customer base, loss of loyalty in
21 their customers.

22 Everybody hates when I use Starlink corn as an
23 example and it's not always instructive and certainly there
24 will never be another grain, so far as we understand from
25 you folks that will be approved for feed, but not for food

1 and that's as it should have been.

2 Starlink is an instructive example about the
3 capabilities and limitations of the grain processing
4 industry, the dry grain milling industry to arrest those
5 kinds of problems after they occur.

6 We are finding that we have very poor ability to
7 fix those problems. Obviously grain is fungible. You can't
8 tell one kind of corn from another by looking at it and one
9 kind of wheat from another kind of wheat by looking at it
10 and often it takes a very sophisticated test to tell the
11 difference.

12 Almost three and a half years after we began
13 testing for Starlink, we are still today testing 100 percent
14 of the corn that comes in to corn mills for the presence of
15 the Cry9c protein. We have tested almost, I have data
16 through the end of January, so the actual numbers would be
17 higher than this, but I have data on more than 374,000 lots
18 that have been tested by my industry.

19 We're testing at a level of sensitivity of five
20 parts per billion and just to put that into context, there
21 are other deleterious substances with known and famous human
22 health consequences, like DDT. The federal limit tolerance
23 on DDT on carrots for example is five parts per million. So
24 we're testing at a level 1,000 times more sensitive for
25 something with no known human health consequences and

1 testing 100 percent of the grain at that level.

2 It boggles our mind that we still find ourself in
3 this position, but there you have it. That's what we're
4 doing. Pure Starlink corn was I believe 12.9 parts per
5 million Cry9C protein and as I mentioned, we're testing at a
6 level of detection of five parts per billion.

7 If you do the math on all that and we have, you
8 find that as of February 1, 2004, the worst case scenario is
9 that the level of Cry9c protein in the U.S. corn supply is
10 3.4 parts per trillion, with a T.

11 I'm unaware of any database on any "deleterious
12 substance" in the food supply for which these kind of
13 numbers exist at those levels.

14 There was one positive detection out of about
15 15,000 samples for the month of January, but that one lot of
16 corn was still illegal and would have caused food
17 manufactured from that corn to be considered adulterated and
18 unfit for human consumption.

19 In the U.S., we like to bash on overseas trading
20 partners for their "unscientific" biotechnology regulations.

21 I would defy you to find a biotech regulation that's less
22 scientifically based than one that says that a substance
23 with no human health consequence at a level of 3.4 parts per
24 trillion causes that food to be rendered unfit for human
25 consumption.

1 I think I'll stop there at those opening remarks.

2 I hope that's provided some context to whatever
3 conversation we have from now and I've got other remarks
4 that I'll make, but I think it's time to give you a chance
5 to respond to anything that I've said or perhaps lay out
6 your plans. I would be interested to hear more about the
7 environmental impact statement in your plans for how you
8 intend to mesh that with your regulations.

9 MR. TURNER: I'll take the last part of your
10 comment about the environmental impact statement and how we
11 plan to use that in the development of our regulations.

12 The environmental impact statement is not an end
13 within itself. It's a means and what we want to do is
14 revise our regulations, using any new provisions in the
15 Plant Protection Act and to address any issues that we know
16 of that have arisen through our years of regulation in
17 biotechnology.

18 For major federal actions often there's an action
19 and there's a plan and you do an environmental impact
20 statement on that plan. I think ours is more akin to a
21 programmatic EIS and we're starting with looking at issues.

22 What are the issues? Looking at options that could address
23 those issues, all in the environmental impact statement and
24 exploring those options of what the impacts would be and
25 then the revised regulation will come after the

1 environmental impact statement.

2 We're looking for an environmental impact
3 statement which is very broad, asks a broad number of
4 questions, with the idea that a very thorough examination of
5 these issues will then inform the writing of the regulation.

6 It's going to be a fairly lengthy process and
7 we're dedicated to doing it as quickly as we can, but we're
8 not going to compromise the process. We're looking to have
9 maybe a draft EIS next fall. Then following that will be a
10 final EIS and a proposed rule at some time after that. It
11 would be some time in 2005.

12 At each of these stages, the draft EIS and the
13 proposed rule, there's more opportunity for public and
14 stakeholder input.

15 MS. SMITH: I think you can expect to see the
16 proposed rule some months after the draft EIS. Go ahead and
17 put that out at that point.

18 MR. TURNER: That's the process overall.

19 MS. SMITH: In terms of your Starlink background,
20 I think it's relevant for folks here in BRS that haven't
21 heard that information from you. What would you have us
22 think about specifically in terms of our regulation in
23 response to the situation that you find yourself into? Do
24 you have any specific suggestions for us?

25 MR. BLAIR: We do. One and Cindy you've heard me

1 ask this before and I think it's still relevant, on the
2 subject of and it seems like it would fit well into an
3 environmental impact statement, is in the case of corn and
4 I'll largely limit my comments to corn because that's the
5 grain in which most of the biotechnology events that we're
6 concerned about happen to be taking place, but I've never
7 heard any kind of consensus on a very simple, but I'm sure
8 difficult subject of how far can corn pollen fly and still
9 be viable?

10 Now I know the regulations used to say a certain
11 number of feet and those regulations have been changed and
12 it's now a broader distance. But honestly, I have had top
13 plant scientists from the very largest corn breeding
14 companies tell me that they believe that corn pollen can fly
15 five miles and be viable.

16 I don't know whether it's a half mile or five
17 miles and frankly I don't much care. What I do care is that
18 seems like that's a pretty obvious one that there needs to
19 be some sort of scientific consensus on it.

20 I haven't done a huge literature search. I have a
21 college degree in agronomy and I am not aware that I've ever
22 heard of any kind of consensus on that point, but that seems
23 like something where APHIS, through National Academy of
24 Sciences or through an ad hoc consortium of top plant
25 scientists and geneticists from land grant universities, you

1 know that you ought to be able to bring some experts
2 together and try and get some consensus on that very simple
3 notion of how far can a corn pollen fly and still be viable?

4 It might be different in west Texas than it is in
5 the eastern states, where it's more humid. In fact, the
6 comment about the five miles that was made to me, they said
7 and that happened in west Texas where it was hot and dry.

8 That to me would be, for starters, that's a very
9 simple but important idea that I think that so much of your
10 regulations are based upon proximity to conventional corn
11 and the strength of those regulations is only so good as the
12 science behind them. I'm not sure that there is a consensus
13 on the science at the moment.

14 MS. SMITH: One point before you move to your
15 next, just to make you aware, that is one of the things that
16 we are planning to do is to have one or more scientific
17 meetings on exactly those kinds of issues. Sally McCammon
18 heads up our office of science and she'll be tasked with
19 planning those meetings in the coming months.

20 Any specific suggestions you have in terms of the
21 scientists that we should involve in those sessions or any
22 specific information --

23 MR. BLAIR: Okay. I would be happy to.

24 MS. SMITH: -- or issues you want to see we
25 address, you can provide that directly to Sally.

1 MR. BLAIR: That's great. I'm glad to hear that.

2 I would be happy to assist in any way that we can.

3 Then the other component of my overall comment
4 would be we all agree that there needs to be scientific
5 consensus and that the regulations need to be based on the
6 best science possible.

7 I mean that's non-negotiable. That's a starting
8 point. However, all the regulations in the world and the
9 most scientifically justified regulations in the world mean
10 nothing to people who ignore regulations.

11 So there's this whole element of human error. We
12 all design systems, whether it's in our computers or our
13 daily work flow or our regulations or what have you. We all
14 have systems and we all try to do the best possible job.

15 But on top of that, there is intentional and
16 unintentional human error, as we have seen in events in
17 biopharmaceutical corn over the last couple of years. There
18 are people who would argue with me on this point I'm sure
19 and there was much praise and back slapping about the arrest
20 of the biopharmaceutical corn that got mixed into the
21 soybeans and then got delivered to a grain elevator and
22 there was much mutual admiration going on about how well the
23 system worked.

24 Frankly, it scared those of us in the grain
25 milling industry. It scared us to death, because yes, it

1 was caught. But, we also might have come a couple of hours
2 from grain elevators doing what grain elevators do, which is
3 to blend grain, ship grain out and if it so happened that
4 your people, or whoever the people were that hadn't gotten
5 there when they did, even if they had been delayed by a
6 couple of hours or a half a day or a day, that grain
7 elevator very well could have loaded those soybeans out in
8 railcars. Into a 110-car unit train, bound for New Orleans.

9 How much different would the resolution of that
10 episode have looked if we were all treated on the evening
11 news to scenes of highway patrolmen stopping a train in the
12 middle of Missouri because it had this illegal plant matter
13 mixed in?

14 I mean I'm not say that that nearly happened. I'm
15 saying it very well could have happened. That situation
16 could have played out much different, in a much more
17 dramatic fashion.

18 That brings me to I guess my second large point,
19 after the science, which is compliance and enforcement.
20 There has to be a dramatic ramping up in the compliance and
21 enforcement effort.

22 I have spoken on programs with some of you in the
23 room and you've heard me say and I've had people disagree
24 with me on this point, but you know the USDA's survey last
25 year that said that on the refuge requirements, that of

1 100,000 farmers in five or six midwestern states, that
2 something like 19,000 of them admitted that they were not in
3 compliance with the refuge requirements.

4 Is that the only thing they're not in compliance
5 with? I mean it would be a bit of a stretch to think that
6 19,000 people could be doing one thing wrong and perhaps not
7 something else wrong.

8 There has to be better follow-up in compliance and
9 enforcement of your regulations or the regulations mean
10 nothing and all that gets me back to the communication
11 component where I started with, which is: People have busy
12 lives and they have lots of things to worry about and they
13 don't want to worry about their food.

14 When they read something in the newspaper or see
15 it on TV that their food might be not safe, it makes them
16 angry because now they've got to worry about it. All they
17 want to know is that somebody is worrying about these things
18 and if they perceive that the regulators and the industry
19 are not worrying about it, it makes them mad because now
20 their attitude is, now I've got to worry about it.

21 Now I've got to try to figure out do I need to buy
22 organic? Or do I need to change to a different diet
23 regimen? Do I need to do something? I don't want to do
24 these things. I've got to get my kid to soccer practice and
25 I've got to do all these other things and doggone it, now

1 I've got to worry about the food.

2 We see it in the water supply here locally now.
3 People are up in arms about that. You know why didn't
4 anybody tell us about that?

5 The communication of what you're doing, the
6 transparency of your regulations, you know most people don't
7 understand biotechnology and you know most people didn't
8 even like their high school biology class and when you say
9 don't worry, all is well, this is based on the best biology
10 and that's not a very comforting and reassuring thought to a
11 lay audience.

12 So it has very little to do with the actual
13 science or the actual safety of what you and by extension we
14 are doing, but they just want to know that somebody's
15 working hard at this and somebody is worrying about these
16 things so that they don't have to worry about them.

17 Whatever it is you're doing on the public
18 communication and you've heard me say this before, you've
19 made tremendous strides. It's much better than it ever was.

20 I think it can be improved even more.

21 MR. TURNER: I want to respond to a couple of
22 things that you've said. First of all, they're great points
23 and I agree with much of it.

24 In terms of compliance, if we talk about insect
25 resistance management and compliance to that, those are of

1 course EPA restrictions of products that we've deregulated
2 in the hands of a very large number of farmers. So
3 compliance is an issue there and one certainly probably that
4 they need to get a handle on.

5 The only thing I want to say is not to mix that up
6 with compliance efforts for things that we're still
7 regulating under permit. A big example is pharmaceutical
8 and industrial plants that we're now inspecting five times
9 per series because it's so important.

10 That sounds defensive and I'm providing that
11 merely for information and I don't want it to sound
12 defensive because we agree totally with your point on
13 compliance and its importance.

14 That was one of the emphasis areas that I
15 mentioned earlier and it's good input and we're now
16 establishing a full-time compliance unit and do plan to ramp
17 our efforts up in this area. It's a tremendous emphasis
18 area. So thanks for that and continued input on that and
19 what we should do specifically on compliance will be very
20 helpful. We share in that.

21 MR. BLAIR: That distinction is a point well made
22 and I take it and say that I think we're in agreement there
23 in that I use that only as an illustration in a case where
24 the stakes aren't that high As you say, it's a deregulated
25 product.

1 MR. TURNER: Not to say that the stakes aren't
2 that high --

3 MR. BLAIR: Not as high as they are in
4 biopharmaceutical --

5 MR. TURNER: It's not as relevant to --

6 MR. BLAIR: -- or industrial.

7 MR. TURNER: -- APHIS in that we've deregulated it
8 and now it's EPA that's putting restrictions on usage of a
9 pesticide. It speaks a little bit more to their program and
10 things which we've deregulated generally are on very large
11 acreages as opposed to the things which we permit per year,
12 which are smaller user group.

13 MS. SMITH: If I can ask a clarifying question.
14 As you're aware, in the March Federal Register notice, we
15 significantly ramped up the compliance on pharmaceuticals
16 and industrials, in terms of everyone involved has to go
17 through an approved training program. John referenced at
18 least five inspections during the growing season and two
19 more after and then increased monitoring all through the
20 tests on our part.

21 Are you saying that the pharmaceuticals and
22 industrials you're looking for compliance efforts to be
23 ramped up additionally or are you saying that there's the
24 communication piece that we need to address, in which we are
25 communicating this level of enforcement that we're doing or

1 both?

2 MR. BLAIR: Both.

3 MS. SMITH: Do you have anything specific in mind,
4 in terms of further efforts to ensure compliance?

5 MR. BLAIR: We probably have some suggestions.
6 I'm not sure they're relevant to an environmental impact
7 statement. One of the things that we have recommended for
8 several years is that companies that are growing
9 biopharmaceutical or bioindustrial corn need to demonstrate
10 liability coverage to make whole those processors or food
11 companies that are damaged by the accidental release of a
12 biopharmaceutical product.

13 The stakes are so high. So long as we have a zero
14 tolerance policy and that was my reason for sharing the
15 Starlink example, it's relevant only to the extent that it
16 shows how hard it is to stuff the genie back in the bottle.

17 Virtually you cannot and so there is no room for error.

18 We don't want to be back here in two years saying,
19 boy were we surprised to find out that here was an area of
20 exposure that we didn't think about. We believe that those
21 areas need to be addressed now, before the biopharmaceutical
22 corn is grown.

23 I don't think we have the luxury of trying to
24 learn on the fly and say, we'll tweak it as we go. We're
25 going to start permitting and allowing the production, even

1 on small scale basis. We're going to permit and allow this
2 production to happen and then we'll continue to revise and
3 tweak as we go along, as the science improves.

4 I'll tell you, we don't have that kind of luxury
5 in our business and one slip-up -- again we understand the
6 societal benefits of more affordable drugs and we understand
7 the societal benefits of the products. But we also have
8 businesses to run and shareholders of the company, as well
9 as the people who consume our products who have I think
10 reasonable expectations that they're not going to get a pig
11 vaccine in their food product or an industrial enzyme or
12 what have you.

13 You know today we don't have that assurance. We
14 can talk about well, yes, in 2003 there wasn't very much of
15 it grown and so on and so forth and that might all be true,
16 but that's not to say that it's not going to change this
17 year or next year.

18 The people that I work with, they say we have two
19 questions. Why corn and why in the corn belt? The biotech
20 companies again everybody likes to sort of hide and rally
21 under the banner of sound science.

22 Let's break this down. Why are they using corn?
23 If you ask them, why are we using corn, the answers you'll
24 get are: Well, we already are in the corn breeding
25 business. Corn is a stable protein. You can store it in

1 silos for years without much degradation.

2 Cost of product is low. You get a lot of
3 production off of an acre. None of those are science based
4 reasons. Those are all economically based reasons. It has
5 nothing to do with science. There's no reason that it has
6 to be in corn.

7 Now you might want it to be in corn, because it's
8 cheaper for you, but that's different. That's not a science
9 based reason for doing it.

10 I've got growing in my window sill a petri dish of
11 duckweed and it doubles every couple of weeks. I'm
12 thinking, why not? Why not? You're well aware of those
13 things.

14 There is no technical reason why biopharmaceutical
15 corn has to be or biopharmaceuticals have to be produced in
16 corn and there is no technical reason why it has to be done
17 in the middle of the corn belt and frankly when I tell
18 people at dinner parties or standing watching our kids'
19 basketball games or whatever and I'm talking to my friends
20 about what I do and if I tell them this, that corn which is
21 indistinguishable from the corn that's going in their
22 breakfast cereal and it's being grown alongside corn that
23 has a pig vaccine, you get this look of, you have got to be
24 kidding me?

25 Again, it has nothing to do with the science. It

1 has everything to do with perception and how people
2 perceive. They may not have ever even been on a farm and so
3 they don't really know how to get their arms around that.
4 Believe me I get mostly nervous laughter, because they're
5 not sure if I'm telling them the truth or not. It fails the
6 laugh test.

7 I had a conversation, it's been three years now,
8 with the CEO of what later became a very famous
9 biopharmaceutical corn company, which experienced some of
10 these problems and he apparently had been warned, boy you
11 know the Millers', they're worried about contamination so
12 you're really going to have to stress the stewardship angle.

13 He put on this very elaborate Powerpoint
14 presentation and he said, we hear your concerns about
15 stewardship and let me tell you what we're going to do about
16 stewardship. We're going to clean out our planters and
17 we're going to clean out our trucks and we're going to clean
18 out our bins.

19 I said, wait a minute. Excuse me for
20 interrupting, but I said, you're talking about growing all
21 of the lysine to produce all the insulin for all the
22 diabetics in America on like 1,000 acres. I said, I think
23 that sounds tremendous.

24 I have a mother-in-law who's diabetic, I said. I
25 think that sounds fantastic. I said, it also sounds hugely

1 profitable. Maybe you could buy your own planters and
2 trucks and combines.

3 I know that that's now part of your regulatory
4 scheme, but it wasn't. That was a major oversight and as we
5 have found out, that company had other major oversights.

6 I don't know what you've asked me that got me
7 started. Why corn and why in the corn belt? This same
8 gentleman I said, and furthermore, why are you growing it in
9 the middle of Iowa? I'm from Iowa. It's a 310 by 200 mile
10 cornfield in the middle of the summer. I said, why are you
11 growing it in Iowa?

12 Why don't you put in an irrigation circle in
13 Arizona and you can have your processing and distillation
14 facility right there? You can grow it under chain of
15 custody.

16 Well, he said, because that would increase our
17 cost of production. I said, if the economics of your
18 business model are ruined by the incremental increase in the
19 cost of production of moving from Iowa to an irrigation
20 circle in Arizona, you've got a bad business plan.

21 You cannot tell me that if you're growing
22 pharmaceuticals that the \$100 or you know couple hundred
23 dollars difference perhaps, I can't even imagine it would be
24 that much, but just for the sake of argument, a couple
25 hundred dollars more expensive on a per acre basis to grow

1 the corn in Arizona than it is in Iowa and that's what's
2 driving your business plan? I don't think so.

3 Companies have gotten very defensive about plans
4 that they have already made and decisions that they have
5 already made and perhaps they don't like undoing plans and
6 they don't like having to face opposition to what they've
7 already planned to do, but I'm sorry.

8 We've got billions of dollars of commerce is
9 transacted each year, based on consumers' assumption that
10 these food products are safe and wholesome.

11 If it's a one-in-a-hundred chance, a
12 one-in-a-thousand chance, a one-in-a-million chance, nobody
13 has ever said, don't worry, it will never happen. Everybody
14 says, the odds of that happening are extremely small. Okay?

15 Granted, the odds of a contamination event may be
16 extremely small, but so is 3.4 parts per trillion is an
17 extremely small number, but it's still illegal and that's
18 where we find ourselves today.

19 MR. TURNER: Are you saying for zero risk with
20 these?

21 MR. BLAIR: We're all rational, reasonable people
22 and we're not saying kill the technology. We've never said
23 that. We're saying, we don't care where you grow it, so long
24 as you can give us certainty that it's not going to
25 contaminate our food.

1 You may say, well you're parsing words and you're
2 trying to weasel out of it. I don't think so. If it's only
3 going to take a few acres, frankly you could grow that under
4 greenhouse.

5 If you say, well that's too expensive, then my
6 response is, okay. Move it somewhere else. You know there
7 are options. It does not have to be grown in corn and it
8 does not have to be grown in the middle of the corn belt.

9 There are options available to you and if you say,
10 well that's going to make it too expensive, too bad. That's
11 not my problem. You're asking me how do we give the
12 greatest assurance that there won't be a contamination
13 event.

14 We may be at opposite ends of the argument as to
15 how this stuff should be regulated, but we ought to be able
16 to agree that growing it in a food crop in the middle of the
17 food production belt is not giving the greatest assurance
18 from a scientific standpoint that there won't be a
19 contamination event.

20 MS. SMITH: Two questions. One, when you say you
21 talk to people over dinner about pharmaceutical corn being
22 grown alongside corn intended for the food supply, does that
23 fact in our one-mile isolation? Does a one-mile isolation
24 not make you feel like it's not being grown alongside, it's
25 kind of a bottom line, out of the food development area?

1 Seed development area.

2 MR. BLAIR: As I said, the one-mile is a major
3 improvement, but there are some people who believe that
4 that's not even enough. But that's just one component.

5 Frankly, I'm confident that APHIS, with whatever
6 outside technical expertise you want to bring to bear on the
7 subject, I am confident that you can come up with a
8 regulatory scheme that is bulletproof from a scientific
9 standpoint. Again, that's only half of the equation.

10 The other half is human performance and accidental
11 contamination. All the regulations in the world, I'll
12 repeat, all the regulations in the world mean nothing to
13 people who ignore regulations.

14 Short of the death penalty, what would have
15 prevented the incidents we saw in 2002? Many of these
16 companies are start-up companies. What are their assets?

17 They've got, in the case of the most famous one,
18 they've got 30-some PhD's, a working farm and they've got an
19 office and probably some computer equipment. Now that I've
20 beat up on them, I guess they probably went out and bought
21 their own planter and tractor and wagons.

22 They've got millions of dollars of Wall Street
23 venture capital funding and if they're responsible for
24 contamination incident, who do we see about that? Who do we
25 go see to recoup our losses?

1 They declare bankruptcy. They close the door and
2 I'm sorry that 35 really smart people are temporarily out of
3 work, but they'll quickly find gainful employment and
4 meanwhile the billions of dollars of cost due to
5 adulteration, brand degradation, lost markets, lost
6 shareholder value, that never comes back. Who do we see
7 about that?

8 That is the point I was making about demonstrated
9 liability coverage, whether that's in some form of a bond or
10 some kind of a demonstrated financial capability.

11 If you can't get a bond, if you can't get somebody
12 to insure your business, then maybe you shouldn't be in that
13 business. We don't operate that way. I can't go out and
14 start a new airline if I decide, hey, I like to fly
15 airplanes. It's my hobby. I'm going to start an airline
16 and I'm going to start charging people to fly them around in
17 my airplane.

18 I've got no liability coverage. I can't do that
19 and there are reasons for that. There are government rules
20 against that and appropriately so. Why is this any
21 different?

22 Why should anybody who is a smart plant scientist
23 with a business plan that they're going to produce vaccines
24 in corn, why should they be allowed to put at risk 100,000
25 U.S. corn farmers, billions of dollars of food products

1 manufactured from their harvest and the potential safety and
2 well-being of everybody who eats those products?

3 I'm a free market capitalist, but I would say that
4 this is an example where government regulation is
5 appropriate. People don't have the right to put at risk the
6 businesses and livelihoods of the entire agriculture sector.

7 Other recommendations: Before any of these
8 products even get permitted for experimental planting, there
9 has to be a test for it. If somebody was producing a
10 biopharmaceutical corn with a particular vaccine and let's
11 say that there was an accident contamination incident,
12 what's the marketplace reaction going to be?

13 Everybody's going to immediately say, all right,
14 corn millers, you have got to provide, in addition to giving
15 me the information on the protein and the moisture and the
16 granulation and all the things that you've been giving me
17 for years and years, you now have got to give me a
18 demonstrated evidence that you have conducted a test for
19 vaccine X.

20 It wouldn't even have to be necessarily true. If
21 an activist or just somebody who had a bone to pick with the
22 biotech industry could claim that they had detected vaccine
23 X in corn food product and believe me, that has happened.
24 Similar events. It will happen again.

25 What would be our reaction? We would have to be

1 able to test for it. We said sorry, there isn't even an
2 approved test method for detecting whether that particular
3 product is in a batch of cornmeal let's say.

4 There has to be a test for these things before it
5 ever gets grown, because that's our only ability. You know
6 the metaphor, once the horse is out of the barn our only
7 ability to try to fix that problem is through testing.
8 That's what we're doing with Starlink. What would we have
9 done if there hadn't been a Starlink test?

10 I can tell you what will happen even in the
11 immediate term, even with the test. U.S. corn exports would
12 go to zero within a day. Would they come back? Eventually
13 over time they will come back to a degree. I don't know.
14 Nobody could predict to what degree. It would depend on
15 what the perceived risk of the product was.

16 Is that 12 months? Six months? Three months? I
17 don't know. But I can guarantee that in the short-term, the
18 corn market would come to a screeching halt. So testing.
19 Liability coverage.

20 We believe that there should be either full food
21 approval or an adventitious presence policy.

22 MR. HOFFMAN: Regarding the food approval, if
23 there was food approval and it was some slight amount of it
24 found in food, what is your feeling about how that food will
25 be perceived by your markets? The people who buy the -- FDA

1 approval.

2 MR. BLAIR: That's a valid point. That's just for
3 starters. We have a chance of giving reassuring and calming
4 messages to consumers, if it's been approved for food use.
5 If it hasn't been approved for food use, we're all going to
6 hang together.

7 My view of the world is this: That as these
8 things are reported, for example, what really outrages
9 people is, as I said earlier, they perceive that people just
10 don't care. That they were just being lazy or lackadaisical
11 or weren't taking their concerns seriously. That's page
12 one.

13 Whether the tolerance is one part per billion or a
14 hundred parts per million or all of that, that's page 38.
15 People don't drill down and look at the technical, in my
16 view, the technical aspect as much as they do they just want
17 to know with a very broad brush, does my government believe
18 that this is safe or not?

19 In the case of the Starlink example, no evidence
20 to suggest that it had any, that's three and a half years
21 ago, no evidence to suggest that it had any human health
22 consequences. Three and a half years later, we've all been
23 eating it. 280 million Americans have been eating it for
24 three and a half years. Still no adverse reaction reports
25 through CDC or FDA.

1 In fact, the one person who thought that he was
2 allergic to it, as it turns out wasn't. But people just
3 want to know that the products are safe. In the case of the
4 Starlink, what happened? What was the immediate reaction?

5 The government paid farmers incentives. We didn't
6 get any. These were people who had legal responsibilities.

7 They had supposedly signed contracts, legal requirements to
8 keep that corn out of the food supply. They failed to do
9 that.

10 They broke their contract. The law was broken.
11 What was the response? The government came in and paid them
12 premiums. I wonder how many farmers got paid premiums that
13 really hadn't grown much Starlink or how many bushels of
14 corn got paid premiums for maybe I grew part of my crop with
15 Starlink, but yes, I put it in that bin with all my
16 conventional corn.

17 What happened to the grain millers who three and a
18 half years later are still holding the bag and still doing
19 the testing and we've lost markets? We can't ship food aid
20 to starving people in India. We can't ship corn based food
21 aid to some countries in Africa. We've lost domestic
22 markets that will never come back.

23 Who do we see about that? My point is, the
24 government has to, I say government but you know everybody
25 has to think: How are our actions perceived? A long-winded

1 way of answering your question, which was: Food approval,
2 do people find that convincing or calming? It would be a
3 lot more convincing and calming than not having food
4 approval, as we have seen.

5 MR. TURNER: Let me spin it a different way. If
6 you did have food approval, but it's something that may not
7 be aesthetically appealing to the public, do you allow it in
8 there?

9 MR. BLAIR: I think that should be part of a --

10 MR. TURNER: Once they come for food approval,
11 some of these and this would be mostly an FDA issue, if it's
12 approved, it's approved and then you have trouble defending
13 scientifically any efforts to keep it out, even though it
14 may be something from a marketing perspective, from a public
15 perception perspective.

16 MR. BLAIR: My assumption is that most of these
17 products could not get a full food approval. But if they
18 can't, again we've never ever said, kill the technology.

19 We understand the market forces at work. We
20 understand that the stakes are too high. You can't open a
21 newspaper these days without seeing a story about high drug
22 costs and people wanting to go to Canada to buy drugs. I
23 mean that whole thing is one of the top stories facing our
24 nation today.

25 It is going to happen. The challenge is, how can

1 we allow it happen or foster it to happen in a way that
2 doesn't put at risk an equally important segment of our
3 society, our food production?

4 Yes. Affordable drugs are important, but so is
5 safe and wholesome food and the way it's being presented now
6 it's like one or the other. My response is: Why is that?
7 Why can't we have both?

8 MR. TURNER: I was just pointing out the
9 complexity of that issue and I think the assumption that
10 most of them could not. It's probably not true for a lot of
11 these pharmaceutical industrial companies. It may not be
12 true.

13 MS. McCAMMON: Sally McCammon. Maybe I can ask
14 the question maybe a slightly different way. You had said
15 that we needed a good AP policy. Do you have some idea or
16 thoughts about what components of an AP policy might be?

17 MR. BLAIR: I'm sure we could come up with some
18 recommendations. I'm not prepared to share any today and I
19 think it would probably have to be risk based and there
20 would probably be some products for which that AP would have
21 to be very low and others there's some things that are
22 already grass or could be that it would be higher.

23 I think that would be a responsible science based
24 policy. It's not a one-size-fits-all sort of thing, because
25 the relative risk, as I understand it, there are many, many

1 different products that are either in development or under
2 consideration and I would guess that we need to have a
3 different AP policy for each of those.

4 I don't know how. That's your line of expertise
5 and not mine, but that seems like that would be appropriate.

6 MR. WACH: Jim, I had a question for you. What's
7 your industry's comfort level with our currently deregulated
8 products? We've talked a lot about pharmaceuticals and
9 industrials, which are under regulation. What about what's
10 already been deregulated?

11 MR. BLAIR: Are you talking about either BT corn
12 and so forth? We support biotechnology. We consider
13 ourselves very strong supporters of it.

14 Those are problematic only to the extent that
15 certain of them cannot be exported or their products cannot
16 be exported to Europe and that's probably a debate for a
17 whole other day. We don't oppose those biotech products at
18 all.

19 The Herculex corn was a good example of a company
20 doing the right thing. You know they held it off the market
21 for an additional year. I think a lot of customer
22 acceptance was developed in that year, even though it had
23 gotten its regulatory approval.

24 They didn't release it for commercialization for
25 commercial production. That was absolutely the right thing

1 to do. That was a responsible stewardship response and that
2 kind of attitude ought to be applauded frankly.

3 But with the deregulated events, they don't
4 present us particular problems other than I said, as it
5 relates to certain overseas markets and that's not a science
6 based problem.

7 MR. WACH: Thank you.

8 MR. BLAIR: We look forward to a day when biotech
9 will have some value based attributes that are important to
10 us. We've been supporting biotech for years and years and
11 years and we understood okay in short-term, the first
12 generation of biotech products, because let's face it
13 farmers are their customers, that the first products are
14 going to be either herbicide resistant or some production
15 value for production agriculture, reduced production costs,
16 whatever and we understood that.

17 We hoped that the second generation would be
18 things that had a value proposition for us: Improved
19 nutritional profile, improved processing ability, more
20 antioxidants. There's all kinds of things that we could, on
21 our wish list of what we'd like to see in grains, we thought
22 that was going to be the second generation.

23 Well the second generation got totally skipped.
24 We went from glyphosate tolerant and BT corn, totally
25 skipped the second generation and went to the third

1 generation, which was vaccines and industrial products.

2 We're still waiting for that first biotech product
3 that has some value capture for us.

4 MS. SMITH: Other questions?

5 MS. McCAMMON: I have one. Sally McCammon. You
6 had said you have to do this testing on each trucks that
7 come in of the corn and I assume that you have developed a
8 system to do this. Do you have a sense of the cost? The
9 percentage that it costs you of your operating system and
10 some of the absolute costs? I don't know if that's the
11 right way to ask the question.

12 MR. BLAIR: No, that's a fine question. We've
13 seen other people estimate those costs. We've never sat
14 down and do it, probably because we fear what the number is
15 and it would make us you know cry.

16 The way that it works and generally in the corn
17 processing industry it is arriving by truck and these are
18 trucks that hold from 900 to 950 bushels and most of that
19 corn comes in at harvest time.

20 That's why we build grain silos adjacent to our
21 mills, because corn is the cheapest at harvest time and so
22 we like to buy as much of it as we can when the market price
23 is low and so that's when we're taking all the corn in.

24 So we like to get it in as quickly as possible.
25 The trucks will be lined up, in some cases city blocks,

1 trying to unload. Historically the way that worked was you
2 drive across the scale. They get gross weight. They'll
3 take a sample for moisture and maybe a couple of other
4 intrinsic quality tests.

5 Then they go. They dump. They come back. They
6 weigh empty and they get a check or it's noted. If it's
7 somebody you do business regularly, you might get one check
8 at the end of the week or something. But at any rate, that
9 whole thing takes minutes.

10 Now the way it works is the truck comes. They
11 take the gross weight on the scale and then they take a
12 sample. Then the truck has to pull off to the side while
13 that sample goes into a laboratory, where people that we've
14 had to hire specifically to run Starlink or Cry9c tests --

15 MS. McCAMMON: It's an ELISA test?

16 MR. BLAIR: It's an ELISA based test. That's
17 correct. There's some grinding and extracting and so forth
18 that goes on. That whole thing takes about 30 minutes.

19 Assuming the test was negative and in the case of
20 January, they were 99.998 percent negative, then that truck
21 is allowed to go ahead and dump its load, get weighed again
22 and away they go. So there has been that slowdown.

23 The cost of the test kits themselves at the moment
24 are being paid for by SLLI, which is the company that
25 Aventis created for this purpose. Their agreement with the

1 12 state attorneys general only lasts through next January.
2 So starting next February, we've got to start paying for the
3 test kits ourselves, unless we want to take legal action.

4 The cost of the test kits is minor, relative to
5 the slowdown in our process and that is minor relative to
6 the lost markets. As I mentioned, you know there are major
7 U.S. food manufacturers who have taken corn out as an
8 ingredient.

9 If you think of your favorite packaged foods that
10 you like to buy, you have probably certain things that you
11 like and you have come over the years to expect a certainly
12 quality and mouth feel and so forth, so food manufacturers
13 really don't like to reformulate, because then they
14 potentially lose somebody whose favorite might be one of
15 their loyal customers, because you love that particular
16 product.

17 They don't like to reformulate. Now that they
18 have reformulated and taken corn out, even if you know by
19 some magic decree we were out of the Starlink testing
20 nonsense, those customers are not going to say, okay, well
21 let's reformulate again and put the corn back in, unless
22 there's some compelling economic reason to do so.

23 They're going to resist that at all costs, because
24 people just don't want to see their products changing all
25 the time. We've lost major U.S. markets and then as I said,

1 in the case of India, the corn milling companies also
2 manufacture the food aid, which is exported under PL480
3 Title II for humanitarian assistance to starving people all
4 over the world.

5 The most common form of that food aid is something
6 we call CSB corn/soy blend and it's corn, flour and soy and
7 it's been fortified with vitamins and minerals. So for
8 example when you see on TV starving people relief efforts,
9 people are lining up to get this powdery substance to which
10 they add water and it makes a nutritious food. That's what
11 that is.

12 India traditionally is a huge market. Market is
13 not the right word, but a huge recipient of that food aid.
14 At the moment, India, as a response to Starlink, won't take
15 U.S. food aid.

16 We're sad about that, because it is business, but
17 it's also morally the right thing to do is to ship food aid
18 to starving people and so we're more sad for that reason.
19 Same thing in Africa. There's some countries in Africa
20 where we've experienced difficulty shipping food aid.

21 MR. HOFFMAN: So this is already revitalized.
22 This is already ground? We've heard people saying food aid
23 was rejected because it could be --

24 MR. BLAIR: Planted. Which of course is nonsense,
25 because it's not hybrid. The offspring of hybrid seeds

1 don't produce substantial crops. That's really kind of a
2 paper dragon.

3 At any rate, we're all familiar with the episodes
4 in several African countries with the bulk corn, but we've
5 experienced the same thing with processed corn products.

6 MS. McCAMMON: I guess I'm curious about the cost
7 of the testing now you see as important to maintain your
8 markets and this is based on a safety issue. If you put in
9 place a testing system and it's twofold, do you have any
10 decision mechanisms for then not doing that testing or
11 ramping down? You ramped up to do the testing to maintain
12 your markets and to assure your customers that you're --

13 MR. BLAIR: Are we still referring specifically to
14 Starlink corn?

15 MS. McCAMMON: That's the example that you are
16 dealing with now.

17 MR. BLAIR: Right.

18 MS. McCAMMON: Do you foresee what kinds of
19 information you would take into account to ramp down? That
20 would have broader implications.

21 MR. BLAIR: Right.

22 MS. McCAMMON: For other things.

23 MR. BLAIR: The reason that Starlink corn didn't
24 get full food approval was because there was some question
25 as to whether it might have allergenic properties. I don't

1 think there's even any pure Cry9c protein left to test.

2 The only way we can envision out of this mess is
3 to say, okay, in 2000 and 2001, when this first happened,
4 when the EPA had its scientific advisory panel hearing in
5 the summer of 2001, we didn't know much about exposure at
6 that time and we didn't know much about allergenicity of
7 Starlink corn.

8 Now three and a half years later, we still don't
9 know a lot about allergenicity, but we know a whole lot
10 about exposure. We've tested 374,000 samples. We know a
11 lot about exposure.

12 Our idea is okay, even if we were to take a known
13 severe allergen, peanut protein let's say and use that as a
14 surrogate, if the calculus is toxicity times exposure equals
15 risk or in this case allergenicity times exposure equals
16 risk, we're willing to say, fine. Pick the most allergenic
17 substance you can think of and if that's peanut protein,
18 peanut protein times zero still equals zero.

19 That's the only way forward that we can see. Even
20 that we have people struggle with the notion of doing that.

21 As I said in the beginning, we're perfectly capable of
22 making of our own mistakes, but when somebody else's
23 mistakes have been imposed on us and have cost us hundreds
24 of millions of dollars, lost markets and just the sheer pain
25 and suffering of having been through this, that has

1 heightened our sensitivity about the risk of accidental
2 release. Whether it's science based or health based or not
3 is sort of irrelevant.

4 Even if the government were to say today: We are
5 lifting the so-called advisory guidelines for testing, our
6 customers have it in their contracts. They would still
7 require testing unless the government's action is dramatic
8 enough, definitive enough to give them the confidence that
9 they can remove it from their purchasing specifications or
10 their contract.

11 If the government were to just quietly lift the
12 testing requirement and not really tell anybody, it wouldn't
13 help us a bit. If the government were to take an aggressive
14 action and say, we've had this policy for three and a half
15 years in an abundance of caution, I've read that a lot
16 lately about BSE, an abundance of caution and when I see
17 what level of testing is going on there, I say you don't
18 know anything about abundance of caution.

19 The government could say, with an abundance of
20 caution, we have been requiring this testing. It is as
21 nearly as can be possibly attained and in the case of
22 February it was zero, but it probably won't always be zero.

23 We'll probably continue to have an occasional positive
24 test. Statistically, the closer you get to zero, the
25 greater the likelihood that they're a false positive, but we

1 count false positives as positives.

2 The government could say, there is no risk. We
3 have been doing this for three and a half years and our
4 analysis shows that there is no risk. End of story. Do
5 that in a strong enough way to give our customers the kind
6 of reassurance that they need that they can take it out of
7 their contract specifications and then we all get back to
8 our regular lives.

9 MS. SMITH: We're going to have to wrap up. Do we
10 have a final burning question? Terri?

11 MS. DUNAHAY: I'm Terri Dunahay. This sort of
12 relates to what you've been saying in your last comment and
13 what you've been saying all along.

14 I get an impression that one of your concerns is
15 that the government or we, USDA, that we really need to
16 improve our communication in a lot of ways and one of them
17 is if we think something is safe, we need to be a lot more
18 aggressive about communicating that. I would like to know
19 if I got that perception that correct and if you have
20 recommendations for the way to get that message out, an
21 effective way to get that message out.

22 MR. BLAIR: Are you a communication person?

23 MS. DUNAHAY: Not really. Not directly. I do
24 international policy. So I talk a lot and I do a lot of
25 proposals.

1 MR. BLAIR: We all talk about things that we don't
2 know about.

3 MS. DUNAHAY: Communication specialist is not my
4 title.

5 MR. BLAIR: I'm not particularly a communication
6 person so I'm not sure that my advice is going to be
7 particularly helpful in that area.

8 I think people who are experts in this area, in
9 the area of risk communication and communicating to the
10 public very complicated or sometimes complicated and high
11 risk ideas I think will say that, as I said earlier, they
12 want to know that somebody's worrying about these things.

13 I think that the people are impressed when they
14 see the Secretary of the Department or the Administrator of
15 the Agency, you know the highest level person.

16 In all honestly, there hasn't been much of that.
17 There's been none of it in the case of the events that we've
18 had, whether it be Starlink or the ProdiGene events. There
19 was very little public communication.

20 They read in the newspaper and the activists of
21 course are very good about leveraging those media events to
22 their advantage, but it's been said nature abhors a vacuum
23 and so does the media, so do the newspapers.

24 In the absence of some calming and reassuring
25 message, that vacuum will be filled by just the opposite

1 kind of a message. I think that more overt public high
2 level communication would, in those incidents, would have
3 really been helpful.

4 The Department had no trouble opening its
5 checkbook and paying premiums to farmers who had made major
6 mistakes in sending that corn to market. Why was that so
7 easy or why was it so easy to come up with \$5 million or
8 whatever it was as a resolution to the contamination of the
9 soybeans in the Nebraska grain elevator?

10 Why was that so easy to come up with millions of
11 dollars, but not easy to just make some calming and
12 reassuring statements publicly? That's free.

13 MS. DUNAHAY: Thank you.

14 MS. SMITH: Just one final clarification, Jim.
15 What I'm hearing from you today I think is a little
16 different than what I heard from you the last time we spoke.

17 Can you just clarify for us again how, in your
18 view, we should be looking at confinement of pharmaceuticals
19 that do have a food safety evaluation and the
20 pharmaceuticals that are seen to be safe to be in food as
21 opposed to pharmaceuticals that lack that evaluation as
22 opposed to those that we know that might have an allergenic
23 contained?

24 MR. BLAIR: I want to read you back. Are you
25 asking sort of follow-up to his question about --

1 MS. SMITH: Yes.

2 MR. BLAIR: -- does food approval make you
3 comfortable? Our preference would be probably to not have
4 to worry about food. Food approval suggests that you expect
5 a contamination incident.

6 Our first choice would be that there be no
7 contamination incident. Now people tell us we can't
8 guarantee that. I've never heard anybody say that to me yet
9 who had a good reason for saying that. We know all kinds of
10 things in life for which zero risk is impossible.

11 There are some things that can be done in this
12 example. What do they call it? Pick off the low hanging
13 fruit. I mean there are some obvious first things that can
14 be done. We're nowhere near close to being at the point
15 where the only thing left is food approval or not food
16 approval and everything else has been buttoned down and it's
17 only that question which is yet to be decided.

18 There are a lot of other things, starting with
19 what is the viability of corn pollen that's been released
20 into the environment? As it relates to EIS, that seems like
21 for me, that would be a great starting point, because
22 everything else kind of builds on that.

23 All of your regulations at the moment about
24 setbacks and buffers and temporal isolation and so forth is
25 sort of dependent on that one basic question. I don't know

1 what the answer is and maybe nobody does, but we better find
2 out.

3 MR. TURNER: Again, we're going to try to get
4 scientific input. There's a major effort along those lines.
5 It's a very complex question. When you first started
6 earlier today, you said something. Maybe you didn't say a
7 simple answer, but an answer to this simple question. It's
8 so incredibly complex and you get below your detection
9 limits after some fraction of a mile. It's a very difficult
10 problem to approach.

11 MS. SMITH: Okay. We need to wrap up. Any final
12 thought or comment?

13 MR. BLAIR: I'll close where I started, which is
14 to say thanks very much for the opportunity. I sense that
15 you are genuinely interested and encouraging in this kind of
16 communication and I compliment you for it and look forward
17 to however we can be of assistance. We would be
18 appreciative of the opportunity to do so.

19 MS. SMITH: Thanks a lot for your time and your
20 thoughts.

21 MR. BLAIR: Thank you.

22 (Whereupon, at 10:30 a.m., the hearing in the
23 above-entitled matter was adjourned.)

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REPORTER'S CERTIFICATE

CASE TITLE: Biotechnology Regulatory Services
HEARING DATE: March 12, 2004
LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: March 12, 2004

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