GES Center AAGES Project
Interviewee: Scott Shore
Interviewers: Fred Gould, Zack Brown
Videographer: Nic Beery
Date: February 21, 2017
Location: James B. Hunt Library, room 4217, NC State University
Length: 1:30:51

[Fred Gould]: **[0:01]** I'm going to start asking you these standard questions, and then we'll switch over to Zack, but we'll both have interesting questions in the meantime. These are all interesting questions.

[Scott Shore]: What's the approximate time length?

[FG]: **[0:13]** We have an hour-and-a-half until 4:00 p.m. or so. That's about what we have—an hour-and-a-half. We just need to get some background stuff. Please tell us your name, your institution and your role.

[SS]: I'm Scott Shore. I work as an independent consultant for Shore Biotechnology Consulting.

[FG]: **[0:41]** Can you describe what you do now? Not in the past—what you do now.

[SS]: I provide regulatory support to clients developing enzyme products and agricultural products. And capacity-building for biotechnology regulatory policy in developing countries.

[FG]: **[1:03]** We'll get into a lot more detail on that. We now need to know, what did you wanna be when you grew up?

[SS]: I wanted to be a football player in the winter, a baseball player in the summer, and a scientist in the spring and fall.

[Zack Brown]: That's a pretty solid answer!

[FG]: **[1:20]** And has that come true? **[Laughter]**

[SS]: Yes, to some degree.

[FG]: **[1:26]** This brings us to the next thing—how did you end up going into the field that you're in now?

[SS]: I've always had an interest in science, and ended up majoring in that in college. Did a post-doc, came to NC State, enjoyed teaching, taught for a while. But because I enjoyed teaching in a major research university, it was a temporary job, so I had four offices, and taught a new course every semester. So when North Carolina passed the North Carolina Genetically Engineered Organisms Act, they had a position opening for a biotechnologist.

It sounded interesting. I applied, interviewed, and that started me on a career in regulatory affairs.

[FG]: **[2:13]** You could've gone in a lot of different directions with your PhD, and you chose not to continue with research, as opposed to teaching. Were you teaching a lot when you were in graduate school? What got you hooked on teaching?

[SS]: I did the traditional—I did a semester of TA-ing that you normally do as a graduate student, and then, when I was in the bacteriology department at Wisconsin, somebody went on sabbatical, and they asked if I could teach their course. And so I taught their molecular genetics course, enjoyed it, and then looked for another opportunity for somebody else who was leaving. Taught a virology course, and then, when I came to NC State—

[FG]: **[2:56]** You were already hooked.

[SS]: Yes.

[ZB]: **[2:57]** You said you liked teaching a couple of times now, so what is it, exactly, that you like about teaching?

[SS]: Transferring knowledge. Keying in on the students who actually see the light, and learn something new and appreciate it.

[FG]: **[3:15]** In that regard, we wanted to know who influenced your career the most.

[SS]: As far as teaching, it was probably my high school biology teacher. He first started talking to me about molecular biology, and transcription and translation. I just thought that was fascinating.

[FG]: **[3:33]** Was there something special about that person's personality that got you hooked, or is it just the subject matter?

[SS]: He made it enjoyable. He was excited about the topic he was doing, and got us excited about it, and it was new, cutting-edge stuff at the time.

[ZB]: **[3:51]** And that was in high school biology?

[SS]: Yup.

[ZB]: **[3:54]** That sounds pretty impressive, it sounds like, to have that.

[FG]: **[3:56]** What year was this?

[SS]: Late '60s— '68, probably, was when it was. We had somebody who had just finished college come in, so he had the most recent stuff and was excited about it. It was an honors biology course, so he was doing stuff—so that set my interest in that area of science.

[ZB]r: **[4:21]** Finally you knew what to do with your spring and your fall, right? **[Laughter]**

[FG]: **[4:28]** So pre-Asilomar. You actually answered our next question—when did you get interested in genetic engineering as a technology? So I guess we heard that. Why did you think the technology mattered, and what do you think was at stake? Especially once you got involved with the North Carolina law—that was a big switch from university.

[SS]: Because I think it offers the opportunity to solve problems, and a different approach than exists with traditional methods. And, as any new technology, there's hurdles to acceptance, and I thought I could play a part in bringing it along, and being sensitive to the concerns people were expressing, and trying to explain how those were being addressed.

[FG]: **[5:20]** So you work in two areas of biotechnology that are very different. One with bacterial products that are in the laboratory, or in the factory, and others that are out in the field. And when you say they could solve problems and could come up with opposition, you have a very different landscape for those two. Could you say something about what you've learned about the difference, and maybe why you think that's there?

[SS]: Between bacterial enzymes versus genetically engineered crops?

[FG]: **[5:59]** Between genetically engineered bacteria and genetically engineered crops. Sorry—I should have made that a little more clear.

[SS]: Because crops get into food, and food is a very personal, sensitive area for many people. And I don't think people realize how much a role microbes play in your food supply. If they did, they might be more concerned. **[Laughs]**

[FG]: **[6:23]** I guess that's what I was wondering about—beer and insulin and—

[SS]: Insulin's a drug, and I think it's been pretty clearly demonstrated that people have a different paradigm when they're evaluating health and drug and disease treatment.

[FG]: **[6:38]** Or laundry products.

[SS]: Yeah. An even more sensitive than crops or animals are human genetic engineering. So I think there's a gradation, and so it's just where you fall on that. I think you'll find some people are opposed to any genetic engineering, if they knew about it, and I think some people would accept any genetic engineering, including human genetic engineering. So I think there's a gradation, and it's trying to find where society is at one point, and how to fit the acceptance or the use of that technology appropriately, within that context.

[FG]: **[7:21]** It's interesting to try to separate out what is food versus non-food, versus field-release, versus factory production, I guess. As I think about the first ice-minus bacteria, certainly met with a lot of opposition, and I wonder if part of that was in the field, and people worrying about it getting loose or something.

[SS]: I think that's part of it, but in talking about food, cloned chymosin—I don't think anybody realizes how much of the cheese is made with a genetically engineered enzyme product.

[ZB]: **[8:03]** Not to dwell on this question for too long, but relating this back to why you think the technology mattered, even when you were in high school, I wonder, was it—probably, knowing myself in high school—was it that the technology was just so cool? Or what was being done in biotechnology was just so amazing, at the time? Or were you thinking, oh, man, we can really solve a lot of the world's problems with this technology? What was the type of thing that really was the primal attraction to?

[SS]: Since you're younger, and I was in high school in the mid-60s, it was before recombinant DNA and biotechnology, so I wasn't thinking along the lines of how it could be used. In high school, it was just the excitement of something new, and how things worked at a molecular level.

[ZB]: **[8:50]** Just trying to understand—the excitement of understanding.

[SS]: Yeah. And explaining how things worked at that level, and being able to have an explanation for transcription, translation, from getting the information in genes, into how it turns into a phenotype. And so just having that explanation was amazing to me. And it wasn't—when I was an undergrad in the mid-70s, when the first recombinant DNA experiments were made, that the first idea of using the technology—

[ZB]: **[9:18]** As a tool of some kind.

[SS]: Yeah. And then not until I was in graduate school, but in graduate school—I was at Wisconsin, and I was working in a bacteriology department, and so it wasn't any real applied thing. It was basic research, although there was—work was going on in Wisconsin was some of the first transformations of plants were being done there. So I was aware of that, but it wasn't—I didn't really think about the use of the technology until I got to North Carolina and actually took that job with NCDA that I started thinking about how it can be applied and used.

[ZB]: **[9:56]** So even at the teaching level, you were still just teaching how to understand the science and the technology, but then once you really got in the—

[SS]: Yeah.

[FG]: **[10:08]** The next question is when did you take your current position, and what attracted you to this work? I guess we wanna just emphasize that we know that you had worked for companies and other groups in government, and now, all of a sudden, you're working for yourself a lot. What was behind that happening?

[SS]: It was the opportunity for new challenge. And getting out of the corporate culture, where you had to do projects that needed to be done because of goals that they had. So as a consultant, you more or less can pick your own projects that you wanna work on. So it was picking things that were interesting. And although I'm working by myself, I still am not

totally independent—so I'm part of a group that works out of the Danforth Center. So I enjoy having colleagues to bounce things off of and to work with and share experiences with. So even though I am an independent consultant, I'm still part of a group. And I think we work together, and working with project teams is still rewarding, as well.

[FG]: **[11:17]** So are there plenty of opportunities out there, when you say you can pick what you wanna work on? Or is it sometimes slim pickings when you're out there? Some people talk about consulting is nervous-making, because you don't know what's gonna happen.

[SS]: Mostly, I'm in a comfortable position financially, so I don't have to press for things. So in the years that I've been one, I haven't had a dearth of opportunities, so I guess I've been fortunate in not having to have to look that much for it.

[FG]: **[11:47]** Or so good that you're desired. We will talk about that in a moment. **[Laughter]**

[ZB]: **[11:52]** So, in brief, how would you say—one of the attractions of your current position is being able to decide what projects you wanna work on, to some degree. So, in brief, what's a project that's an example of something you would like to pursue, versus maybe something that you'd be less interested in pursuing? If you're taking about the corporate culture, what's something that maybe—?

[SS]: It's being able to work in developing countries and solve problems that are facing them, like the virus resistant cassava. There's a disease in cassava—that's not a crop of importance in the U.S., but very important for smallholder farmers in Africa. And so, being able to, hopefully, impact that in some way is a new opportunity. Working with the gene drive and the malaria control is just a fascinating new application that is an enormous problem that could be helped by the use of the technology.

[ZB]: **[12:54]** So maybe not being tethered to commercial applications completely.

[SS]: Right. Doing another Bt crop is not something I'd be interested in doing. Although, when I did work—but I think my career has been—I don't know whether I have ADHD or I just like new challenges. I haven't stayed at any one place for longer than seven years.

[FG]: **[13:18]** We were told it was five years. **[Laughter]** We were told you'd take any job, as long as it wasn't for more than five years.

[SS]: It's always looking for a new challenge in what you do.

[FG]: **[13:30]** Some of these things you've answered, so we don't have to go through every question, but it's a little different for you, because it's not about research. You were involved with a lot of the key people in regulatory affairs early in your career, when you first started working with the NCDA. Can you talk a little bit about those people? One thing we want to get at is things that you might remember about certain people that really influenced you or were role models. And also, in the end, we do wanna know if you have ideas for people that we should be interviewing to understand the history of Ag biotechnology

regulations. So, if you could just start with, who was the most role-model-like person for you, in this whole regulatory arrangement?

[SS]: For understanding regulatory were three people—it was Howard Singletary and Bill Dickerson at the North Carolina Department of Agriculture, who'd been in state government for a long time, been involved in regulation and oversight of agriculture in various programs for a long time. So it made me appreciate what needed to be done to work for the various constituencies who'd be involved in implementing the law and the regulations. And then Terry Medley, who was head of the USDA biotechnology program at the time. And the way he worked with the state government officials, and how he brought them into the federal process, which was in contrast to the way FDA and EPA were working at the time. So it was very helpful, as a state regulator, to be able to work with the federal regulators, and understand what kinds of things they did, how they did them, why they did them, and being included in the process.

[FG]: **[15:24]** We imagine that you also came in contact with a lot of other very important people who had a stake in what happened, and I imagine being that biotechnologist for the USDA, and further in your career you've had to come up and hold your own in conversations with a lot of powerful people.

[SS]: I try to avoid conflict. **[Laughter]** I let other people get into that.

[FG]: **[15:55]** So were you successful at avoiding conflict? Or did you ever have to deal—?

[SS]: I think for the most part, I was.

[FG]: **[15:59]** And how did you manage that?

[ZB]: Yeah, that's a lesson I think for a lot of people

[SS]: You listen a lot—

[ZB]: **[16:06]** Change jobs every seven years. **[Laughter]**

[SS]: You pick projects that are less controversial. You build coalitions on points of agreement.

[FG]: **[16:20]** Talk a little more about that. With the North Carolina law and everything else, certainly you had to build coalitions.

[SS]: I can think of several instances. I can remember one of the first meetings I had with that was me, the counsel for the Department of Agriculture, and industry representative, and an environmental representative, talking about the regulations and specific language, and how we were going to put that together. And, of course, the industry person is on one end of the spectrum, environmental is on the other, and I'm trying to figure out, along with the legal counsel, how we're gonna write something that works. And so it was listening in that meeting, not doing anything—not agreeing or disagreeing with either one of them, and then going back and talking with the legal counsel, and Howard and Bill, and trying to

come up with something that we thought we could defend and represent to both extremes of that, and then work with and implement.

[FG]: **[17:31]** And that worked?

[SS]: Yeah, I'm sure that both the environmentalists and the industry were upset with us, but I've often said that means you're doing a good job in government.

[ZB]: **[17:42]** Were there any other examples of people bringing suit under the act? Contesting—

[SS]: One of the decisions was challenged. One of the things the law had was an appeal mechanism, so the Department of Agriculture could issue a permit, and then a party could appeal that, or deny a permit, and a party could appeal that decision to the genetic engineering review board. So the Department of Agriculture was given the authority to issue or deny permits, but then that was subject to appeal. So there was a permit granted for the testing of a genetically engineered tobacco that was producing trichosanthin, that was for AIDS treatment, I believe. A small company that was doing this in North Carolina, in collaboration with some people at NC State. So it was a field trial being done on an NC State University research station. We issued the permit, it was challenged by environmental groups. We had a hearing, presented the case, and the decision was upheld.

[FG]: **[18:54]** Actually, I think it would be useful for you to go back a little more and talk about the genesis of the North Carolina law, so we'll have some context on the law. I know we just talked about it, but give us some detail on it.

[SS]: The U.S. federal regulatory system was establishing a coordinated framework to determine how to oversee biotechnology. So this coordinated framework came with—the conclusion was that the existing laws could be used to regulate biotechnology, and so the agencies, USDA, EPA and FDA were charged with coming up with plans for how they would use their existing laws to regulate the products of biotechnology after 1986 and the coordinated framework. They took time, and in the late '80s had not yet formulated a complete strategy, so many states felt unsure of the situation. Some companies felt unsure of the situation, and the public did.

And so North Carolina, led by the North Carolina Biotechnology Center, put forth an effort to have a state law that would lay out clearly a path for the testing and eventual commercialization of products of biotechnology. And so they passed the North Carolina Genetically Engineered Organism Act—the general assembly did—were done by the Biotech Center with a lot of other people involved—industry as well as public health interest groups. University—I don't know who else because I came on after.

[FG]: **[20:30]** And you mentioned that you had to have the sunset clause in that in order to get it passed.

[SS]: Right. The general assembly passed it, but it was only given support by industry if it had a sunset clause, which meant after five years, if it wasn't reauthorized by the general assembly, it would cease to exist.

[FG]: **[20:47]** And so, when you came in and read this law, and that you were supposed to develop into regulations and all of that kind of thing, did you say, oh, that was a good job? Or did you see that it was sort of pieced together and could've been more efficient or anything else?

[SS]: I think the law was good, and like many laws, they're general principles. So it's more in the interpretation of those principles that it got hard when it came to developing the regulations. And then the form that would be out there for people to fill out. The permit—what information they would have to submit. That was the hard part, where it got contentious between environmental activists and industry.

[FG]: **[21:28]** And do you know how many total permits were put out for field releases?

[SS]: No. Those are things I can go back and check, probably.

[FG]: **[21:37]** But do you think it's more than ten?

[SS]: Oh, yeah.

[ZB]: **[21:39]** Hundreds?

[SS]: Yup.

[ZB]: **[21:41]** Is it more than 100, would you say?

[SS]: No.

[FG]: **[21:45]** So somewhere between ten and 100, order of magnitude.:

[SS]: Again, this was before commercialization, so these were all field trials that included university field trials that are very small plots on university research stations. And some commercial field trials that were done on farmer—or, in some cases, company farms that were done out there. So this was the first trials of Bt cotton, some Roundup Ready soybean—

[FG]: **[22:13]** And tobacco. **[Laughs]**

[SS]: Virus-resistant tobacco. Bt tobacco.

[ZB]: **[22:20]** So North Carolina was one of the first states to pass a law like this? Were they the very first one to do this?

[SS]: Yeah. And the first one to institute an actual system.

[ZB]: **[22:28]** Why do you think that is? What were the conditions that made it appropriate for—why did North Carolina jump into this?

[SS]: I think it was more the biotech center and the industry.

[FG]: **[22:38]** I think it was the biotech center, and also, I think that Charles Hammer must've had some leadership role—the head of the Biotech Center—to have a vision, because there was also that kind of—when I was on that committee for this guy, I was just a side-player on that. But it seemed like there were some people who wouldn't have wanted it at all. And I think they worked on it to get it—but the question—what other states had state laws?

[SS]: Wisconsin, and Minnesota, and Maine.

[FG]: **[23:19]** And did they seem to follow the—

[SS]: They didn't all hire a person. Some used an existing person, and some required just that the state sign off on a federal decision. Ours was the most comprehensive.

[FG]: **[23:37]** When did those other laws come in? Did they fall—?

[SS]: Around the same time, the '90s.

[FG]: **[23:49]** Did you ever move from lab science into administration? **[Laughter]**

[ZB]: Actually, that's a good **[inaudible 23:55]** on the transition. When you got to the Department of Agriculture, you were the first biotechnologist to be there, you said. What was the communication like? Was there a learning curve early on, when you first started trying to be—?

[SS]: For me, or for them?

[ZB]: **[24:09]** For both. For both sides.

[SS]: I think there was for both. Just understanding what the department does, and how much they do to facilitate agriculture and other activities like the tree nurseries, plant nurseries, plant pests, noxious weeds. Bees—the bee person was in our department. Testing seed. So much that they do, I wasn't aware of, and how much they do, both to protect and promote agriculture, and try to ensure safety of products that go out. For them, it was trying to understand what this biotechnology was all about, and breaking it down into what it would mean for a crop and how it performed, and trying to get them to appreciate the mechanisms, although some people were more interested in that than others.

[ZB]: **[25:14]** So your experience as a teacher before that position, that would seem to me would be—did you use some of those skills that you developed as an educator?

[SS]: I think so. And so the Department of Agriculture had specialists that were distributed throughout the state, so they could administer their program, and so they'd bring them in. Probably twice a year we'd have meetings to go over all the programs, and so I usually had a slot in that, to try and explain biotechnologies, and talking about that. So I enjoyed that, and most of them were interested in finding out what was going on.

[FG]: **[25:49]** It was pretty new. Some of these questions are more aimed at heavy-duty researchers, but one thing that does come out here is that you were involved in this all the way back to before anything came out into the field, and I'm thinking about, around the year 1996 to the year 2000, you probably saw what was happening and you had some kind of a vision of how this thing would progress. And here we are, 20 years after the first release. Would you have envisioned that we would have what we have now, or something different, in terms of the numbers of crops, numbers of traits, whatever? What's it like now, compared to what you might've expected then?

[SS]: The first thing I think of is with Novozymes in the enzyme industry. I wasn't thinking about crops, and where things got to. But even in the 2000s, when I started thinking about crops and stuff, I guess I would've thought it wouldn't be as controversial; that safety would've been demonstrated, and people would've accepted it, and it's just another technique used for crop improvement.

[FG]: **[27:05]** And when you go back to when you helped with the North Carolina regulations, did you expect that it would sunset, and then everything would get—people would accept that things were easier, even at that time?

[SS]: When I initially took it, no, I had no idea. It was clearer after the three-and-a-half, four years, that things were moving in the federal government. That there wasn't gonna be a need for it.

[FG]: **[27:33]** No, I'm not really talking about just the North Carolina law. That's when things started, when you were regulating, and how stringent the regulations were. Did you feel like, even then, over time, that things would be relaxed? As you were saying, in the year 2000 you were thinking they would be accepted more.

[SS]: USDA was always looking to streamline and do risk-appropriate assessments, so they were looking for classifications that could have reduced requirements, and they went to a notification system. So they did adapt their system to I think be proportionate to the risk, that was done. FDA always has—because they don't require premarket approval, they always have had a risk-appropriate approach, I think. EPA I think ended up doing more than I thought they would, as far as the requirements that they have. So if I think back of what I would've expected then, again, my interactions were mostly with USDA, and so I was more involved in their process, and I guess adopted that, and saw the rationale behind that, and supported that, too.

[FG]: **[28:54]** That's that one piece of it, and the other part was that you thought that the opposition to it would slowly melt away a little bit more?

[SS]: Yup. I still was enough of a scientist in thinking that rational thought and scientific explanation would—but since then learned that that isn't what it's all about. It's an emotional decision.

[ZB]: **[29:20]** So that does lead to—I think this is an interesting question, whoever wrote this here: if you could make an optimism curve about various points in your career. I'm not sure exactly what this means, and I think you can interpret it however you want. **[Chuckles]** But I would think, when were you feeling most optimistic about both you career, and the trajectory of biotechnology, and when were things not looking so good, if you looked at the whole span of your career, I guess.

[SS]: It's an interesting question. I think I was optimistic the whole time I was in NCDA, because things were moving forward. Things hadn't come out yet, but the research was showing progress, field trials were going on, companies were developing stuff. When I went to Novozymes, I was in a different area, but still watching things. So things were starting to develop then—I was still optimistic. Vector Tobacco was a whole other world when I was in that.

[ZB]: **[30:20]** It sounded, from the earlier presentation, that there were quite a few controversies and difficulties, it sounded like, for the company.

[SS]: Yup. But that was more just being in tobacco, and being a small entrepreneur, and Ben LeBow being the person he was, and already inciting the big companies to work against him. So that was more tied to the specific company and product they were working on.

[FG]: **[30:44]** Could you just say a couple of things about Ben LeBow—what kind of person he was? Do you think that came out of—he was just feeling ethically compelled to do what he did with about tobacco, and telling people about addiction and nicotine and all of that?

[SS]: I think he was ethically compelled, and he also got a good business advantage out of it.

[FG]: **[31:10]** Okay. That's what I wanted to understand. **[Laughs]** Then we could differentiate those two easily, I guess. Because it's always interesting, because he seems to be quite the character.

[SS]: Yup. He's a successful businessman, but he also wanted to do some good. I think he sincerely believed that this might help people stop smoking.

[ZB]: **[31:32]** And there was a business opportunity at the same time.

[FG]: **[31:36]** I was thinking, though, earlier, when he first came—because he didn't have a new company coming when he said that.

[SS]: But he got out of the penalties that the other tobacco companies got imposed on them.

[ZB]: **[31:46]** But it was still a potentially calculated decision, from an economic point of view.

[SS]: Can I go back to one thing we were talking about?

[FG]: **[32:01]** Yeah. Always do that.

[SS]: Back in the late 1990s, when the first Cartagena Protocol meeting took place, I was in the enzyme industry then. We had heard about it as an industry group and talked about it, and couldn't believe that they were gonna potentially stop us from sending genetically engineered organisms and enzymes, and had to [be] subject to that. So I was concerned about that, but didn't get involved in it. Since then, following that slightly, I think that's made me much more pessimistic on the possibility for global acceptance of the technology. And then I—

[ZB]: **[32:46]** So specifically pessimistic about the global acceptance?

[SS]: Uh-huh. And I was at the meeting in Cancun in December, so that was the first one that I attended, the conference for the Cartagena protocol. It was depressing with the bureaucracy of all the countries and all the delegates, and then the activist organizations and within our group trying to influence things and get information to people. And then listening to the discussions. I mentioned in the talk today about wordsmithing for that one, and I can remember—it must've been two hours, them talking about in the report, whether they were going to accept, note, acknowledge, and several other words, on a report of their expert committee. And so it's—

[ZB]: **[33:37]** Very difficult.

[SS]: Yeah. And just hearing all the people and what they believe about genetic engineering and what's being done, that I know isn't true, and how that's being used against adoption of the technology for what I believe are useful, good purposes without risk to human health or the environment is depressing.

[ZB]: **[34:00]** Are there any key factors you can think of, in terms of when the Cartagena Protocol was originally being developed and what you're talking about? Anything that could've been done differently to avoid some of the problems that we're seeing?

[SS]: I don't know, and that's international negotiations that I'm not expert in. I don't know how you avoid—

[ZB]: **[34:16]** For example, did the group feel too big or too small, or was the organization appropriate for getting the right—

[SS]: The U.N. seems like a difficult place to hammer things out, as opposed to just continuing, let them proliferate.

[FG]: **[34:34]** Do you think if the first products didn't come from multinational corporations, the Cartagena Protocol would've looked differently?

[SS]: I don't know. I don't believe so, because I think some groups have an agenda that is just against new technology, and it's an easy one for them to latch onto and use to their advantage. And not all groups oppose; some of them are responsible and say some applications are fine, some require more assessment. But there are enough groups that are vocal and use the opportunity regardless of whether—

[FG]: **[35:18]** So you think in the international arena there's a lot of that?

[SS]: Yes. Then I think the GM papaya that was developed by—

[FG]: **[35:28]** Gonzales.

[SS]: Yup, in Hawaii. It benefited both growers of the GM and other growers, and has no potential effects. But it being opposed there, as well as it being stopped in other countries where it was trying to be adopted is an example. It's not a multinational, but if you're saying if it was—

[FG]: **[35:55]** If the Gates Foundation was the first one to do this for cassava—

[SS]: The Gates Foundation is getting railed on as well.

[SS]: **[36:05]** I know, but I'm saying before all that, if cassava was the first thing, or golden rice was the first thing out of the pipes, as opposed to pesticidal cotton or something like that? I don't know. I wonder what—

[SS]: **[inaudible 36:18]** I guess I don't think so, but I can't turn back the clock.

[FG]: **[36:23]** It is interesting, when you say they're against technologies, but I don't see too many protests against—well, now you do—Google or—there are so many things in the internet and new technologies, IT kind of stuff that there's been very little protest against, which is affecting people's lives dramatically. That's an interesting question. Anyway, I don't want him to harp on that. Let's keep moving.

[SS]: Those driverless cars might be interesting. That's a new technology.

[FG]: **[36:54]** But that bring up again—is it the newness, or the specifics of the technology that people respond to?

{ZB]: What roads did you not take in your career, and do you have any regrets?

[SS]: Not continuing on a research path. **[Laughter]** No regrets about that, because I wasn't very good at it. It's a tough one to do. My wife is a research scientist.

[FG]: **[37:26]** When you say you weren't good at it, were you just not good at it, or was it kind of boring to you, or was it tedious?

[SS]: It was tedious. I was tired of beating my head against the wall, and keep doing experiments, and then looking forward to constantly finding funding for what you're doing—it's a challenge. And there's so many good people coming up with good ideas, and I was at good places, so I was seeing these people all around me who were brilliant, and I just wasn't brilliant. **[Laughter]** But I enjoy explaining their brilliant ideas and experience, and teaching it.

[ZB]: **[38:01]** Which is a separate skillset. There are people who have trouble translating what they know into education.

[SS]: But yeah, I wish I could've been a football player and a baseball player.

[FG]: **[38:14]** Did you ever play in high school?

[SS]: Yeah, I played high school football and baseball, and I continued playing softball up until a few years ago. Now I enjoy doing skiing.

[ZB]: **[38:29]** I'm with you on that one.

[SS]: Still active.

[ZB]: **[38:33]** Even from North Carolina.

[SS]: Well, no, I go out to Colorado. **[Laughs]**

[ZB]: **[38:42]** I think it would be good to get on the record just a little bit about what happened with when you were describing earlier today, about the tobacco with the Amish group, and your involvement in that. So just a little vignette, a little anecdote from you about what happened there I think would be good to hear.

[FG]: **[39:00]** Not just from your personal experience. We know you came on a little bit after, but tell us the story.

[SS]: Mark Conkling, a researcher at NC State in the genetics department was working on root-specific promoters and realized that nicotine is synthesized from the roots of the tobacco plant, and if he could knock out one of the key enzymes in that pathway, he could make a nicotine-free plant. And that potentially might be used as a smoking-cessation aid, to help people get off of cigarette smoking by removing the nicotine, but still allowing them to have the cigarette and the social interaction of smoking. So you can unlink the two and combat the addiction in two steps that way.

And so the license was taken by Ben LeBow, the executive head of Liggett Tobacco, and he started a company, Vector Tobacco, to make no-nicotine cigarettes using this GM technology that Mark had developed. And so Mark had gotten a plant that was no-nicotine, but it was GM tobacco. Ben LeBow, because of this previous stance against the rest of the tobacco companies had endeared their hatred, and so they essentially got all

the growers and the largest tobacco-producing states not to accept growing any of the Vector tobacco, GM, no-nicotine tobacco.

So the company went to Pennsylvania and the Amish farmers, who had a long history of growing tobacco, but with the reduction in smoking in the U.S., their market share was going down. And so they had lost an important cash crop that were important to them and their livelihoods, and sustaining their families and their farms. And so they welcome the opportunity to grow this tobacco and get a guaranteed source of income. And so Vector Tobacco grew I guess hundreds of acres of GM, no-nicotine tobacco in Pennsylvania Amish communities. It was grown, harvested and stored at Vector Tobacco sites, and then processed into cigarettes.

[FG]: **[41:20]** You showed us that picture of a horse-drawn tobacco planter, and genetically modified seeds—

[SS]: Yeah. Seedlings getting put in the ground.

[FG]: **[41:33]** And you also said that you did have discussions to explain to the farmers what this was.

[SS]: Yup. There were grower meetings that were organized by the company to talk about, in general, what it was we were doing, and then specifically, what had to be done to be grown under USDA permit. And how the crop was going to be handled, how the seedlings were gonna be distributed, what applications of fungicides and insecticides they could do, how it was going to be harvested, how they were going to get paid, and all those things. And addressed any concerns or questions that they had.

[FG]: **[42:08]** And you were at those meetings when that was happening?

[SS]: No. They were primarily run by our LEAF operations group. I was there just if there were regulatory questions.

[FG]: **[42:16]** Do you know if there were some farmers at those meetings who really were worried or concerned in any way?

[SS]: None of those—

[FG]: **[42:26]** The people who showed up were the ones who wanted to do it, you said.

[SS]: They were in the program and wanted to.

[FG]: **[42:32]** And how many years did that go on?

[SS]: At least two or three.

[FG]: **[42:37]** And then the product didn't—?

[SS]: The product didn't succeed in the marketplace. It had limited marketing in only a few states, and it never took off for a variety of reasons. One was probably—the only tobacco that was no-nicotine was Burley tobacco, and American cigarette is made up of Burley, flue-cured and Turkish tobacco. Burley is the worst-tasting tobacco, so when you had a no-nicotine cigarette, it was all burley. So they tried to overcome that with some flavor additions—additives. I've never smoked, so I don't know, but people said it just wasn't a very good-tasting cigarette.

[ZB]: **[43:20]** It's like non-alcoholic beer or something.

[FG]: **[43:23]** Right. Like a Flavr Savr tomato. **[Laughter]**

[SS]: The other thing is nicotine addiction is very powerful, so even if people tried to get off, they'd go back. So what the marketing people did is they came up with—Quest was the brand name of the product; Quest one, two and three. So it had the level of a light cigarette nicotine, and then half that, and then none. So when people were trying to step down, people would go from one, to two, and back to one, to two, to three, and then back to two. And so it never worked the way it was supposed to. At that time, also, it was before FDA had control over tobacco and cigarettes, but the attorney generals were raising a stink that the company was making medical claims with it being a smoking-cessation aid. So FDA had no control over cigarettes and tobacco, but if you were saying you were curing nicotine addiction, that was a medical claim. And so there was always a fine line that the company was trying to walk in how they were presenting the product. So all those reasons.

[FG]: **[44:30]** I would think that a tobacco executive like that would know that he couldn't sell something made of Burley tobacco. **[Chuckles]**

[SS]: Well, they were working, and they did get some flue-cured and Turkish, they just hadn't been ramped up in production. And they were trying flavors to mask it, and they were also trying things to imitate the nicotine hit. I guess people who smoke get a nicotine hit—they can tell it's nicotine, so they tried things like caffeine, capsaicin—

[ZB]: **[45:06] [Laughs]** Wow. Spicy.

[SS]: Yeah. Just to mimic some kind of nicotine hit.

[FG]: **[45:12]** And were they doing whole new transformations of the other types of tobacco?

[SS]: Yes, for each—?

[FG]: **[45:20]** Each one they would've not backcrossed**.** Because that would've been a little hard.

[SS]: I don't think you can backcross flue-cured and Burley.

[FG]: **[45:26]** I don't know. I would think you might be able to, but it would be a mess.

[SS]: Yeah.

[ZB]: **[45:32]** On the regulatory side of that story, was there ever a potential need—I'm just wondering with the Amish, would there ever need to be an inspector that goes out to their fields or something, form the U.S. government?

[SS]: Yeah. As a matter of fact, USDA—**[chuckles]** the people at the Biotechnology Regulatory Service were excited about this, too. They had a trip—they came from Washington and met us, and we had a tour of several of the farms where they were growing the tobacco, so everybody—and USDA permit applications would go to usually one biotechnologist to review. So they had their whole staff come to see what was going on. So they did that. But they're also obligated as part of the permit conditions to have inspections at various times, so they did that.

[ZB]: **[46:20]** That would've been such a fascinating meeting to watch, with the Amish and the USDA inspectors, I would think. Are there any cultural—is there any concern—was there ever any issue with the Amish farmers, with having the USDA inspectors out there?

[SS]: Not that I was made aware of. My experience, having been an inspector and also worked at companies where USDA has come to inspect, there's always some sensitivity when you're getting inspected. I think the people I had experience with at USDA were not the kind that were antagonistic when they'd come and do inspections.

[FG]: **[47:16]** I think that this issue about—you've had people who are critics of genetic engineering, and you sort of say that some of them are making up stuff out of the air, in a way. But are there some of them who you do respect and feel that use facts, just maybe somewhat different interpretations. Do you have people that you would respect in that—?

[SS]: I can think of two people who, early on, when I was with NCDA, showed up at the state federal conferences, and also were involved in many of the issues, were with the Environmental Defense Fund. So, Rebecca Goldburg and Doug Hopkins, who was an attorney for them. And they always seemed rational and real. But I haven't followed to see what happened to them, but they're no longer working against the technology, **[chuckles]** and EDF is not doing anything.

[FG]: **[48:13]** Right. Rebecca Goldburg got into fisheries and other things.

[SS]: And Doug was doing a lot with fisheries. They're doing important work, and I think some of them genuinely felt that there were things that needed to be worked out, and I agree that there were.

[FG]: **[48:28]** And what about the folks from the Union of Concerned Scientists from way back? They were involved just as long as EDF.

[SS]: I think they talked like they would support things that were good, but they always seemed to oppose everything and qualify any kind of support that they gave. So that's the way I've seen Marti Mellon and Jane Risler.

[FG]: **[48:54]** And do you think that when they spoke, they were factual or not factual?

[SS]: No, I think they were generally factual. I think they were, but the way they couched it—I guess the biggest issue I have is the way people raise speculative concerns about risk, about potential products that might develop, and not separating that from the existing products that are out there and have been evaluated. Conflating the two confuses people who aren't familiar with the technology and the products.

[FG]: **[49:34]** And one of the things, just to bring it back a little bit, is that, when you're talking about cassava or other things—Uganda—is there a lot of people who oppose that with the idea not that there's anything wrong with that product, but that that's really a bigger end-game of a Trojan horse kind of approach? So I'm sure you've faced that, in terms of these other products that could come down.

[SS]: That's the inability to separate the two. Even if Monsanto is using that as a strategy, you should still evaluate that cassava on what it can do for the smallholder farmers and the resistance to a devastating viral disease, regardless of what might follow on after that. Fight that battle when it happens. Evaluate this product and its potential impacts.

[ZB]: **[50:23]** That does raise a question I have for you—you're talking about capacity-building in areas where they don't have biotech regulation, or not very much. Is there risk that if they don't develop that regulation sufficiently before they bring in a product that is demonstrably beneficial, that that might end up being a Trojan horse, because the capacity is not sufficiently developed? That you let this one good product in, but then you have ten bad products follow it, because you haven't really set up the—I guess, have you ever seen a situation where maybe it makes sense even to just wait for the introduction of a good product which everybody knows is good, just so that you can make sure the institutional structure and capacity is there for the future? That's a layered question.

[SS]: I guess I don't feel comfortable dictating what products should and shouldn't be developed. I guess the way I'm trying to approach it is do as much capacity-building as I can, as fast as I can, in as many places as I can, and support that so that they're ready for whatever comes.

[ZB]: **[51:32]** Hard to argue with that. So your answer is, don't take an orientation towards a specific product, but just towards the capacity in general. Makes sense.

[SS]: That's a tall order, though. **[Laughter]**

[ZB]: **[51:56]** The flip side of the opponents who you respect is, are there some that—on the flip side, some of those pro-genetic engineering have seemed dismissive and prone to hyperbole. How do you view these people, or have you encountered people like this compared to the opponents who you respect?

[SS]: Yeah, there's many in the industry, and the industry line is it's the panacea that's gonna feed the world, and I've hated that since the beginning. And there's any one of a number of people who've spouted that. Also, there was somebody early on at Monsanto—Frank Serdy was in their regulatory affairs department, who was just dismissive and obnoxious to both state regulators and any opponent of technology, and I didn't appreciate that.

And I guess seeing that also realized the impact that that had on me and others, as well, and that it's not gonna accomplish anything. And seeing more the collaborative—even if you disagree, at least listening to other people is gonna get you a lot farther than his approach. Henry Miller, who was at FDA when I first started and is now at the Hoover Institute, I think also is dismissive of—my first meeting, essentially told me North Carolina was crazy for establishing a law that was of no use whatsoever, and has, since then, always railed against opponents of the technology and regulation of the technology. So I guess, again, I'm somewhere in the middle on this.

[ZB][: **[53:46]** You've seen both extremes, it sounds like.

[SS]: Yeah.

[FG]: **[53:48]** But you specifically pointed out this thing of the feed-the-world kind of thing. Right from the beginning you saw that as problematic. Why is that?

[SS]: Because I don't think one thing can solve that problem. It's involved with infrastructure, it's getting food around to all the people, and it's not one crop and one disease, or one pest that's impacting the ability to feed the world. And so you can't possibly solve it all with biotechnology.

[FG]: **[54:22]** Yeah. I was just watching a video of the CEO's of Monsanto and Bayer shaking hands, and they're gonna make their companies together, and, again, said that thing about feeding the world. So I wonder, why is that still the mantra?

[SS]: Because it's an easy, appealing message that they think works. I don't know, but it never worked, from the very beginning, on me. **[Chuckles]** And I didn't even have an understanding of why it didn't work. It just didn't sound right. Also because I know enough about science and doing technology that it never works always as first-envisioned; it's always more complicated to accomplish something.

[ZB]: **[55:06]** I guess one thing I'm hearing from you—just bouncing this off you to see if I'm hearing it correctly—the feed-the-world message is not required to argue for using this technology. That's not necessary in order to pursue some of these things.

[SS]: Yeah. It's just one tool of many that you have to use to improve agriculture and crop improvement**.** And it has to be used in concert with everything else. And I think plant breeders understand that, for them.

[FG]: **[55:39]** I think during the Green Revolution there was a little bit of that same kind of arrogance—it was the plant breeders who were gonna save the world, and then everybody else was contributing a little bit, but that one gene that turned things into semi-dwarfs. So it's interesting, we scientists can have our—

[SS]: Yeah, it's true. It's not unique to biotechnology, and I'm thinking they have the technical solutions.

[ZB]: **[56:06]** Even on new biotechnologies, are you concerned with the direction, the way the rhetoric's going, that we'll fall into the same kind of extreme polarized trap that we had?

[SS]: And I also think it's foolish to think if we do the new technologies and leave no trace of genetic modification, that people are gonna accept it as not being genetically modified. As being a way around the regulation—I just think that's foolish. Naïve, that that's going to work. You can tout the fact that it's more like natural breeding and selection, and you will not leave any trace of foreign DNA, so it might ostensibly be safer and easier to evaluate, but don't say it's not modification by other means.

[FG]: **[57:15]** You mentioned Serdy and his approach, and we've heard Robb Fraley say, oh, man, we screwed up; we shouldn't have done it that way. Do you think that they really have learned? Do you think there's a change in the attitude of the companies?

[SS]: Not having been in a company for eight years now, I don't know. I think companies, by and large, are driven by trying to put a product out there that they think fulfills a need. And they're also—as you well know, they picked things that were easy, technically, to do first. And so that's what they did. Even before GM crops, the first thing Monsanto did was BST, because it was a very easy one to do. And they didn't, I think, appreciate the kind of reaction that would get. So I think they're better in anticipating, and they've incorporated more communications and stakeholder engagement people early on to gauge the reaction it might get. But I think they're still gonna be driven by what the market is for a product, and the potential use and profit is of it eventually.

[FG]: **[58:35]** You mentioned that they had picked the low-hanging fruit, and Major Goodman would back you up on that one—he always said that they didn't pick the low-hanging fruit, they picked the stuff that was on the ground. **[Laughter]** I hope we don't have to cut this out of the tape. But he said that at the National Academy, so it's not like I'm revealing something. But I guess the more serious question is that it is hard to do genetic engineering, and sometimes people act like it's easy. So with golden rice, we've heard people say, if it wasn't for the protesters, we'd have golden rice ten years ago. And other people say, it's not the protesters; it's just that they haven't made a good rice yet. What do you think about that, and how hard is it to make something like that?

[SS]: I think for nutritional crops it's much harder, because it's more than an expression of a single trait, and so it's a complex pathway, and it potentially can affect other physiological factors of the plant. I haven't worked on the golden rice project myself, and I wasn't working on it when I was at Syngenta, or Ciba, or whatever it was then. So I don't know the details of what could've been at some point. But I agree, your general thing—it's

harder than people—especially when you're talking about plants as opposed to microbes, getting back to bacteria and fungi.

[FG]: **[60:12]** Can we go back to the bacteria and the fungi? Because there aren't that many people who've worked in both of these roles, so I do want to come back to that a little bit. Especially the rennet thing—people don't know that they're getting rennet that's made by bacteria and is genetically modified. They also probably don't know that up until that started happening, it was a calf stomach that they were having to deal with, but nobody's ever talked about that, and I am kind of curious. It would seem like that would be kind of appealing, to be able to have a message that you no longer have to get enzymes out of a calf's stomach in order to make your cheese. **[Chuckles]** Maybe that just wouldn't be appealing, but at the same time, with the other enzymes and things like that, that are being used, or could be used for beer or yogurt—

[SS]: Another one Novo touted is stonewashed blue jeans. So the way jeans were made to look stonewashed is they were washed with stones—giant tumblers of stones that, environmentally, they had to mine it. Also, the energy to run the fabric through that and do it, as opposed to having a little bit of liquid and cellulase enzyme that would accomplish the same thing, and create the same look. So environmentally, it's much more benign. But people don't—

[ZB]: **[61:57]** It's quite a **[inaudible 61:57],** I thought of Green Chemistry, actually, based off of this.

[SS]: Yeah. And Novo as well as the other enzyme companies do that a lot.

[FG]: **[62:05]** Right. And organic jeans are kind of in, like organic cotton for jeans.

[SS]: Yeah. What about it? I doubt that they use—I don't know how they—

[FG]: **[62:18]** I have no idea if they can do that stonewashing.

[SS]: This is off the topic of biotechnology, but that's also one thing that's upset me—talking about organic cotton, and if it's grown in Arizona, how much irrigation is done to that organic cotton that's environmentally damaging?

[FG]: **[62:39]** These are all these kind of other peripheral issues. So, as you said, it's not a rational thing; it's an emotional kind of thing. But all I was getting at was I don't see anybody having played out the positive emotional content for some of these products, just like what you just said about the stones, or about not having to kill calves. Whatever other kind of things. I'm a vegetarian—I love the fact that you eat cheese—vegetarian cheese. Five percent of the American population, and probably a larger proportion of people who are concerned about GM are vegetarians. I don't think many people know—I don't think anybody knows—it's a rare thing. But I guess people think it's like the third rail to touch it maybe. What do you think?

[SS]: I don't think it's very interesting, and I'm not sure—in some areas with the cheese, you can still get microbial rennet. So you can make it from a non-engineered—then make an enzyme that's not chymosin, the cheap rennet, that you can use. So it's a non-engineered microorganism with a non-engineered enzyme, and you can make it that way, so it can be vegetarian.

[ZB]: **[63:52]** So you potentially can have non-GM vegetarian rennet, is the punch line.

[SS]: But I don't know what—

[ZB]: **[63:58]** The market for that is.

[SS]: Yeah.

[ZB]: **[64:01]** Don't tell Whole Foods, because they'll start marketing that instantly, like on day one, I would imagine.

[SS]: But in all the lectures I give at NC State, I use chymosin as an example, and the enzyme companies always tout their green chemistry, and enzymes as a preference to mostly chemicals in applications.

[ZB]: **[64:32]** Do you think that message works?

[SS]: It works for them, but the general consumer—it doesn't impact them. So it may impact a detergent manufacturer who wants use an enzyme instead of a chemical and say that it's more natural, or other customers—

[ZB]: **[64:53]** Because it is funny that you don't see a similar analog in genetically modified crops with Bt—reducing pesticide use through genetically modified crops. It just seems like the same advantage there would be kind of easy for somebody to pursue as being green. And I guess people have—I don't know if people have tried to tout the green benefits of Bt crops, but that would seem to be—

[SS]: I think people have.

[ZB]: **[65:21]** Yeah. **[Chuckles]** It doesn't work.

[FG]: **[65:27]** So in the African situation, where there really is a lot of—

[ZB]: **[65:32]** That's true, we haven't talked about that. So much of his regulatory experience in Africa—a good topic to close with

[FG]: **[65:39]** I was going to ask something beyond regulation, just because we were talking about the controversy. In Africa there is a lot of controversy over genetically engineered crops. What kind of things would open—other than teaching and infrastructure-building, what would let the African countries make better decisions for themselves?

[SS]: I think have a product that addresses the need to have a crop that it's important to their smallholder farmers. That's why I think the VIRCA project is in a good position, because it's a disease that's specific to Africa, that is devastating, that doesn't have an alternative solution or way to deal with. So getting that product out I think will make a difference, and having farmers and consumers see that.

[FG]: **[66:40]** How soon do you think that might—

[SS]: We're hoping in the next three-to-four years to have it through. We've started our first regulatory field trial.

[ZB]: **[66:58]** I wanna back up a little bit, given your current position, working a lot in African biotechnology regulation. One of my first questions here was just, how did you get into that realm from—how did you parlay what you'd been doing before into this work?

[SS]: When I was looking to leave Syngenta and talking to colleagues who'd been out of the corporate environment, there were two people who were doing consulting, and both had been working at the Program for Biosafety Systems, which is a USAID-sponsored effort to do capacity-building in developing countries—Africa as well as Asia. And so they had been working on programs and doing that, and so I talked to both of them about it, and they said there was an opportunity there. It was interesting, challenging, sometimes-rewarding work, and a whole lot different than being in a company. And then shortly after I made that decision is when Gates funded the Biosafety Resource Network at the Danforth Center to actually support a group of regulatory experts to provide regulatory assistance to the research projects that they were funding.

[ZB]: **[68:19]** So then watching—it seems it sounds like you've seen a lot of the development of biotechnology regulation in Africa, in general, in particular countries. So when you think about what happened in the U.S., and also in North Carolina specifically—the trajectory of biotech regulation here—how does that compare to what's been happening in Africa? Were they going in a different direction, or what, in general, are some kind of structures that they're—

[SS]: It goes a lot slower. And North Carolina developed quickly because the Biotech Center and individuals put together a good coalition of people. They had a defined purpose, they had a scope, and they were working with a state government that was willing to work with them as well, as well as an agency that was willing to take it on and administer it. In Africa, what I'm seeing—and this effort has been going on since the early 2000s, that people have been trying to facilitate this. The Cartagena Protocol started some of it, and the U.N. started a program where they were trying to develop things, and PBS came on board and has been doing workshops and trying to do it.

It's been very slow-going—there are only a few countries that have laws and regulations and actually have confined field trials that they've been doing. A few countries have actually approved crops, so it's just much slower. It gets involved with the challenges of just general governance in Africa, and the political situation of most countries, and the instability of it. And so oftentimes efforts will be put forward, but then there's a change in

the government, or a change in the priorities of that government, so biotechnology is not a high priority. There's not a lot of support for institutions, including the ministries that administer laws and regulations, so it's difficult to actually have something in a framework for actually putting it into effect. So it's mostly very slow-going.

[FG]: **[70:33]** I don't know if you can comment on the mosquitos and Burkina Faso. Burkina Faso was one of the first African countries I think to have GM cotton. So is there something about their government that makes them more able or wanting to do that?

[SS]: Yeah, I think they're people who want to try new technologies and see the advantages for their farmers and their people.

[FG]: **[71:01]** So why Burkina Faso compared to other countries?

[SS]: I haven't been in there long enough to know the culture of it. I know one individual who's the head of the National Biotechnology Committee/Authority who's very good. Listens very well and understands what's been put forward as risk assessment, and how it should apply, and has people on that board who also understand and follow that.

[FG]: **[71:38]** What about with the mosquito work, as opposed to the genetically engineered crop? Were you involved in the regulatory—moving that through to get—?

[SS]: We participated in a meeting where they had a draft of the application for the contained use, so that was reviewed by the committee, and so it was presented by the PI in Burkina Faso, in Africa, and who was doing the work and would do the work that would take place in the laboratory that he oversees. And they were allowed to ask questions about stuff. It was explained what kind of experiments would be done, what kind of containment there would be, what kinds of standard operating procedures and protocols would be in place. And so it was going through—all that application was, I think, helpful for them. Preceding that—actually, backing up with where we did play a role is the Biosafety Resource Network sponsored a trip by the Burkinabe regulators, as well as Mali and Kenya was a country the project was working in then.

So they brought regulators, government officials, to the U.S. to visit two labs that were doing transgenic insect research. So they got to visit two laboratories in the U.S. We also arranged for meetings with U.S. government officials; I got to meet with FDA, who currently was overseeing**,** you know, release of transgenic mosquitos. Unfortunately, the trip was at the end of February and there was a snowstorm, so we couldn't get to meet with USDA as we were schedule to do. But just being able to see the labs and see how it was handled here in the U.S., being able to talk to the FDA officials I think gave them some comfort as well, as to what was done. So I think that gave them confidence to evaluate this application for contained use, and, as well, to do the follow-on, which was a Burkina Faso committee conducting a workshop to help the Malian regulators evaluate coming applications for contained use in their country.

[FG]: **[74:06]** And I guess that requires that the Burkina Faso people and the Mali people trust each other.

[SS]: Yup. So that was also—it's fortunate that I think it was part—they're adjacent countries. They're both French—ex-French colonies, so they're French-speaking, and people on those committees had known each other just professionally through scientific and government interactions before. So it was a natural thing that we took advantage of, but that's the kind of thing you have to look for, and that's how you build capacity. **[Crosstalk] [Laughter]** But it wouldn't have happened without support from outside, because neither country has the funds or the initiative or are rewarded for doing something like that. So it was us working with ABNE, the African Biotechnology Network of Expertise to set up that meeting and provide the funds for the travel and the site, and facilitate that interaction.

[ZB]: **[75:12]** Yeah. So, to catalyze that. That does go to the question I had before, too, about the demand for the countries to have more biotechnology regulatory capacity. Where do you feel like that's being driven from? From the citizens of those countries, or is it driven by the desire to get donor funds, say, from the Gates Foundation, where Gates wants them to have these regulatory structures?

[SS]: I don't think it's coming from the citizens. I do think people in government wanna have that, because they wanna be in a position where they can make a responsible decision. So they see the need to become more educated, to understand how systems work in other parts. So I think part of the drive comes from them. For the workshops, in many cases they get paid for attending the workshop, so it's not an ongoing fun thing, so they don't go for that. So I don't think it's incentive that way. They do get a couple days at a hotel. But I think their motivation and their request for it is because they wanna be able to understand things. I think there are also outside Africa governments who wanna facilitate it because they want acceptance of the technology. I think that companies sponsor some of these things, and CropLife is an industry-funded organization that has some activities along this line. So I think it's a combination of things. I don't think it comes from the citizens wanting that.

[ZB]: **[76:48]** Yeah. I was wondering how you'd respond to that. **[Chuckles]** And you also mentioned on the Target Malaria, on the genetically modified mosquito work, containment protocols being an important part of that. I wonder—this relates to one of the questions here in terms of, where do you think genetic engineering policies associated with it are going in the future? So specifically in Africa, maybe you're thinking about gene drives and things like that. What are some of the discussions going on in Africa about these technologies and potential regulations for them in Africa?

[SS]: For gene drive?

[ZB]: **[77:26]** Yes.

[SS]: It's just getting started. I don't think they've thought a lot about it, and that's one of the things we're working with NEPAD and ABNE to do. There was a workshop last fall that was the first one that I'm aware of in problem-formulation for gene drive in insects. And there's plans to have another one—that was held in West Africa; there's plans for one in East and Southern Africa in the summer. And then there'll be continuing efforts to do that.

Our group is also going to try and do another study tour for release. So we have contained use, so we're gonna try and get them possibly to go to Brazil where there's been release of a genetically modified—not a gene drive, but a genetically modified insect—the Oxitec mosquitos there. So have them visit both the facilities there, and then some of the release sites and talk to the regulators in that country.

FG]: **[78:31]** That sounds pretty important. That'd be interesting. So to go back, a lot of this depends on trust, and I just wonder where these two Pan-African groups of scientists stand in terms of even the public knowing they exist or trust in these organizations? I was surprised when I found out that they were—

[SS]: ABNE? I don't think they're as widely-known as they should be or could be.

[FG]: **[78:59]** Maybe you could tell us a little bit about your experience with them. How are the members selected? Is it a merit-based system or is it political or—?

[SS]: It's merit-based, as far as I'm aware, and I'm not involved in the selection process, so I don't know. The African Union supports NEPAD, and then ABNE is primarily supported by Gates. So they give direct funding for that.

[FG]: **[79:32]** So there are two—do they have overlapping ownership?

[SS]: Yeah. NEPAD is higher, and, besides the biotechnology, has also some medical stuff to it that they're trying to do, and just technical—any kind of technology is what NEPAD's supposed to evaluate for, and promote development of that.

[ZB]: **[79:52]** So ABNE sits underneath NEPAD, but then they're getting money directly from Gates.

[SS]: Right.

[FG]: **[80:01]** What is your impression—how many people are in the smaller group?

[SS]: NEPAD is—I don't have any idea. All I know is—

[ZB]: **[80:10]** They're pretty extensive, I thought.

[SS]: ABNE is four or five people.

[FG]: **[80:18]** That's it?

[SS]: Yeah.

[FG]: **[80:19]** Okay. And those people adjourn from different parts of Africa?

[SS]: Yeah. The head of it is now in Dakar, Senegal. The administrative guy is still in Ouagadougou, Burkina Faso. They have a person in Uganda, I think, for East Africa, and they have somebody in South Africa.

[FG]: **[80:40]** So nobody from Burkina Faso—

[SS]: No, there is somebody from Burkina Faso. He's not a scientist, he's the administrative support, but does a lot of the facilitation.

[FG]: **[80:50]** Okay. The reason I'm asking is about—if trust is a pretty big issue here, it's really important that they somehow get known and also remain trusted.

[ZB]: **[80:59]** They have accountability when they go into these countries.

[FG]: **[81:02]** Are they pretty aware of their role, and how to maintain that kind of thing? That's another part of—

[SS]: They're building on improving on it.

[FG]: **[81:12]** More to be known, or to maintain—

[SS]: To develop their expertise and to be known and get out there and do training on their own. Initially, they were trained, and now they have to—

[ZB]: **[81:23]** Do the training.

[SS]: Right. So it's partly getting them up so they can train people. It's being done in concert with the U.S., and there's an Australian who's been working with them, too.

[FG]: **[81:39]** So do you feel like they're competent, and now they have enough training to do the training? Because it's not like the game of telephone.

[SS]: We're still working with them.

[FG]: **[81:49]** So do you have optimism about that?

[SS]: Yeah. I think we're making progress and doing things. **[Inaudible 81:57]**

[FG]: **[81:57]** Any other questions?

[ZB]: **[82:01]** We could ask a couple of closing questions, just taking it back.

[FG]: **[82:04]** Okay. One of the things we always ask people is, is there anything that we didn't ask you? We could leave that until later.

[ZB]: **[82:11]** Yeah, I've got a couple more before that—at least one more. Actually, this just occurred to me: what would've happened—I'm just trying to put myself back in the

Genetically Engineered Organisms Act with the North Carolina state government back in the day—I keep trying to remember how old I was at that point. **[Chuckles]** I'll save you all that **[inaudible 82:30]**. But what if you had received, at that point—what if the technology had developed differently, and you'd received applications for something like gene drives, or something that had a much bigger potential to spread through the environment? Can you imagine how that would've been received or handled? How you might—you were in the position of essentially writing these regulations, so, based on your experience, can you imagine how you would've written that, or approached that situation at the time?

[SS]: I don't know that the regulation itself would've been written any differently. I think the risk assessment would've been much more difficult, I think. Even now, the amount that is known in predicting what's going to happen with that is—

[ZB]: **[83:16]** Challenging.

[SS]: Yeah. Then, it would've been even less, so I really couldn't imagine it going forward. I don't know that I would've had enough information to be comfortable, at that point.

[FG]: **[83:35]** Now we can ask the final question of questions. What haven't we asked you that you'd like to tell us about? Think about it for a minute.

[SS]: I think you've done a pretty good job.

[FG]: **[83:50]** This is gonna go down in history. **[Laughter]**

[ZB]: That's the idea.

[FG]: **[83:56]** So you can thank your mother, you can—**[chuckles]**. You're somebody who's been involved in this regulatory stuff, and interestingly, from lots of different angles. What do you see? Is there anything else, like advice or anything that you would say? I don't know; maybe there isn't.

[SS]: It's just reiterating. Don't oversell it; listen to all sides. Something I said in the lecture, though, is the government people are trying to do a good job, and ensure things are introduced responsibly and safely. I don't think that gets across enough. By and large, I think the bureaucrats—and I was one for a while—get short shrift in all this.

[FG]: **[84:57]** Actually, I do wanna follow up on that, because you brought it up before. A lot of people see the government bureaucrats being influenced heavily by the companies—by the people on the street in Washington lobbying and stuff like that, as well as just a heavy hand of politicians pushing things. Some people would say that we saw it the opposite way with the salmon or something like that—there's a lot of politics in that, and a lot of people would say that the regulatory people who were trying to do their good job are not part of this problem, but that they don't get to do their job right because of that.

[SS]: Yes, I've seen that happen. Politics does influence things. Despite trying to set up laws and regulations and make responsible, science-based decisions, sometimes politics intervene. Is that what you're asking?

[FG]: **[85:57]** I guess what you're saying is, people should know that government agent people are trying to really do a good job, make sure that things are looked at carefully and get them out. But for the person and the public who thinks that salmon has been sitting on a shelf for so long, it's the government people who've been holding it back, right? So how do you separate the people who are doing the scientific assessment from the others? In Europe it's pretty easy, because you have the food safety—EFSA, and then the European Commission, or whatever it is. So you could see what the regulatory people did, and then you could see what the politicians did. But in the U.S., it's a little hard to differentiate that.

[SS]: Yeah. I guess I see through some of that, having been involved in the system. So you don't understand what's happening sometimes—

[ZB]: **[86:55]** From the public's perspective.

[SS]: Yeah. You don't always see that. But as bad as our system is, it's still better than most, and so I don't think I'd encourage every bureaucrat to go out and describe what's happening behind the scenes; I think that will make the whole system dysfunctional. I think it's better that sometimes you have to swallow your pride and do something that you don't necessarily agree with, but you try and institute procedures and other things that will maybe anticipate that next time, and allow you to make a decision and do something that you think is right.

[FG]: **[87:36]** So the regulator's job—I don't know what you wanna call them—the person who's doing the scientific assessment—

[ZB]: **[87:42]** The bureaucratic oath or something? **[Laughter]**

[FG]: **[87:45]** But it's a hard position to be in, sometimes.

[SS]: Yeah, it can be very difficult, and I don't think they get enough credit for what they're doing. And I think sometimes industry tries to push too much on those regulators, and I've found, in my experience, it may just be because of the products and companies I've worked with, it's been more beneficial to work with those regulators. And it may take a little longer, but you usually get what you want, and you build credibility and trust—

[FG]: **[88:14]** If you don't go outside to push them.

[SS]: Right. And you don't antagonize them. **[Laughter]**

[ZB]: **[88:24]** That does create the question I have about the—from a regulator's perspective, you're saying their heart's in the right place, basically. In their capacity, at least in the U.S. system, or the state governments, is there enough of an incentive for them, professionally, to strike that balance? Because they're getting messages from both industry and critics,

but within their jobs, how do they know whether they've done a good job, I guess? **[Chuckles]**

[SS]: Usually it's not an individual; you're part of a bigger agency. But let me say, also, within that agency, there may be differences of opinion on any one subject, and there may be differences at the scientist level, versus the administrative level, too, that sometimes come into play. In my interactions, I've always found that people are trying to assess all aspects of it and then come to a decision that they are charged to make, by the law and the regulations that they have to work under, which is also sometimes forgotten. They're limited to what they can do because of their legal restrictions.

[ZB]: **[89:43]** And I know you always hear that the best compromise is one where everyone is unhappy, but unfortunately, that means the regulator has sort of made everybody unhappy in the process of doing their job. And as an economist, I'm like, it would be nice if they got rewarded for doing their job well.

[SS]: I think sometimes they feel good when they make a decision—they approve something, or, in some cases, they deny something that turns out that is appropriate to deny.

[ZB]: **[90:10]** Then they feel vindicated.

[SS]: Yeah. I think for most bureaucrats, that's enough, knowing that they have made that decision. And there's enough people, I think, in industry—even though some are antagonistic, there's enough who do appreciate it and at various venues, do give them a pat on the back for doing the right thing.

[ZB]: **[90:31]** Particularly since there's a lot of overlap—you're been in both positions, and a lot of people have—

[SS]: Yeah. And people go in both directions.

[FG]: **[90:40]** All right. Thank you very much.

[ZB]: This is a fun discussion.

[FG]: **[90:45]** Yeah, excellent. And thank you for taking a little—

[Nic Beery]: Pleasure. I always enjoy listening to these conversations. **[Laughter]**