PROJECT: GENETIC ENGINEERING AND SOCIETY HISTORY PROJECT
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INTERVIEWERS: MATTHEW BOOKER, BRAD HERRING, AND ALISON WYNN
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[00:00:00]
[Matthew Booker]: This is the Genetic Engineering and Society History Project. It is the 5th of October, 2015. Matthew Booker, Allison Wynn, and Brad Herring are here with Greg Jaffe. Please tell us your name, institution, and role.

[Gregory Jaffe]: So my name is Gregory Jaffe. I'm the Director of the Biotechnology Project at the Center for Science in the Public Interest, which is a nonprofit consumer organization located in Washington, DC.

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[M.B]: And, what do you do? Tell us about what you actually do.

[G.J.]: So, I run the Biotechnology Project, which is just myself and a part-time assistant and we—it's involved with genetically engineered food. So genetic engineered crops and animals that might enter our food supply and all of the issues around that; so, issues of the science around that, the benefits, the risks, the regulatory oversight of that in the US but also abroad. And so, an attempt to give consumers good information about this technology, ensure that it's properly regulated, and ensure that it's safe.

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[M.B.]: And so, what sorts of activities do you engage in on a daily basis?

[G.J.]: So, there are a host of activities. They range from talking to the press and media to providing them both background information, as well as on [the] record information for stories; providing lobbying congress when there is relevant legislation in this area; trying to get the—understand the regulatory oversight by the different regulatory agencies in Washington, as well as providing comments or suggestions to them on ways to improve their regulations; reviewing their decisions on different specific products and providing comments when they have comment periods to do that; drafting articles, writing op-eds for general newspapers as well as peer-reviewed articles for journals on the topic.

I spend about a third of my time internationally so, helping developing countries primarily in Sub-Sahara in Africa and Southeast Asia; understand both biotechnology, genetically engineered crops, and biosafety regulation, and the international agreements in this area, as well as how they might implement them

at the national level. So, I'm sure I'm missing a lot of other things, but that's just a smattering of some of the things I do.

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[M.B.]: So, this is going to take you back a ways, but is that what you imagined you'd be doing when you were a kid?

[G.J.]: Not at all.

[M.B.]: So, did you have a vision for yourself as a kid? Do you remember what you wanted to be?

[G.J.]: I don't. My father's a lawyer, and so, I've ended up being a lawyer. I guess I was exposed to lots of lawyers growing up, so it was a logical career path to go into law, although my father wasn't a typical lawyer either. He didn't have a law practice; he didn't work in a private firm. He worked either in the government or in academia or in foundations.

So, while I was brought up in a house that talked a lot about policy and law, it was not necessarily the kind of—he was not a lawyer who worked in private practice. So but, other than that, I always had a strong interest in science and math, and those were the subjects I was good in. So, I both had this interest in law and government and policy, but also had this very strong back—strong ability to do well in math and science.

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[M.B.]: So, when you were in—when did you begin to move, or, I should say, how did you move from that interest towards specializing in math and science? Did you major in these topics as an undergraduate?

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[G.J.]: So, I applied to college and said I was going to be a chemistry major, but I'm not sure I ever really expected to be a chemistry major. I got to Wesleyan University in Connecticut. My technical advisor that year was a chemistry professor who I loved, and he was great. But, I decided to become a biology and government double major, and I think there was only one other person who has ever majored—at least at the time, who had majored in biology and government. She actually was a woman who was on my same freshman hall.

But, I loved both biology and the science, learning about the science. I wasn't real big on doing research in the laboratory. That wasn't where my interest was. So, while people said to me, ”Oh you should become a doctor,” I'm like I'm not interested in becoming a doctor. I wasn't interested in being a Ph.D. scientist, but I was very interested in learning about biology in particular at Wesleyan University. I don't think we ever studied anything larger than a

cell. So it was all molecular biology, cellular biology was not a whole organism biology.

But, I also was very much interested in government and in policy and so I decided at a place at Wesleyan—you had the opportunity to do something like double major. So, I double majored in both those departments.

And then I decided I wanted to do a thesis and I wanted to a thesis in both of those departments by the end of my junior year. And search for topics, and I actually came up with a topic of recombinant DNA research and genetic engineering, and the [regulation and] oversight of it, the regulation and oversight of that. And, I had looked at a number of articles, and this was my recollection from 30 years ago, and this is now dating me as to how long I've been involved with this issue and how old I am.

But, I noticed that there were either—most of the stuff that had been written at that point to date—this is 1983 was either scientists writing about the scientific issues or the government or lawyers writing about the legal issues, and there wasn't one person who had brought both of those disciplines in any kind of written writings that I was aware of.

So, I decided that was what I would do. I would write an article—write a thesis on the—it was entitled *Recombinant DNA: The Question of Regulation* for both departments, which was a little challenging because there was no biology professor who wanted to be my thesis advisor. They all wanted bench scientists and I ended up writing to Earl Hanson, who is a biology professor at Wesleyan and had a science society program and he was on sabbatical in Hawaii and that summer I wrote to him and asked him to be my thesis advisor, despite the fact that he had never met me before, and I had never taken a course with him. And, he agreed, and I got a—it was also trouble—difficult getting a government professor to be a thesis advisor, and I ended up getting a new professor, Barbara Craig, who was just coming into the university, so she had nobody else to be a thesis advisor to and was willing to take me on.

But, because it was this interdisciplinary thesis that really didn't fit anywhere it was a little difficult and, for a time, frustrating, but I said I'm paying a lot of money at Wesleyan. They believe in this kind of interdisciplinary [work] and creating your own majors, and so forth and so on. There should be no reason why I can't do this thesis on the topic. And so, I ended up writing my thesis on this topic, which is how I started learning about it.

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[M.B.]: Were there mentors who helped guide you in those years as an undergrad, or was this really coming out of your own explorations?

[G.J.]: So, I can't say that there wasn't—I mean I had both of those professors who ended up being really good thesis advisors and giving me lots of advice and learning the topic along with me. But, neither one of them knew this topic, so we were all learning it for the first time. But, they clearly were helpful, and I appreciated them working with me, somebody who they didn't know on a topic that might not have been their choice for somebody to do a thesis on. So, I can't say there was anybody. But, Wesleyan did have a very advanced biology program at the time, and so I took a couple graduate-level biology courses including one in Genome Organization, so I felt I was getting the scientific background I needed from Wesleyan.

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[M.B.]: So, then you graduated from undergrad and what happened next?

[G.J.]: So, as I re-entered undergraduate I looked for a job, and I looked for a job in Washington and the ideal job just happened to pop up. I applied to be a research assistant at the Congressional Office of Technology Assessment, which was one of the four research arms of Congress at the time, and included the General Accounting Office, the Congressional Research Service, and the Congressional Budget Office.

And, the fourth was OTA—the Office of Technology Assessment, and they did long-term meaning they did studies that averaged 18 months in length, and they had a—my recollection is they were organized into nine branches or divisions. I don't remember what it was called. And one was the Biological Application Program, and that was the program that had done to that date some of the foremost studies on biotechnology, and I used some of those in my thesis, which is [how] I knew about them. And so, they had a position available – not for a study on biotechnology or genetic engineering – but for a study on alternatives to animal use and research testing and education, and I applied and got the position as a research assistant on that project.

And so, I left Wesleyan, and within a week of graduating I started in Washington, DC, working on Capitol Hill in this department helping draft this report, and so I was with people who were some of the experts on biotechnology and genetic engineering. We were all in the same office, but I was working on a different—each project had a staff of four or five people.

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[M.B.]: So, this is the mid-1980s at this point?

[G.J.]: This would be June of 1984. So, I went there and worked there for a year—a little more than a year on the study on alternatives to animal use and research testing and education. I wrote the chapters on institutional care committees and on some of the regulatory stuff. There were other people who wrote—worked on some of the other chapters. When I say wrote, we did this in conjunction with an advisory board of people who were experts in the area. But, being in that office, I

got to learn a lot about biotechnology, and I got to work with people who were working on those projects. So, I did that for a year, and then I went back to law school.

[M.B.]: And, why did you make that decision? Do you—why leave that exciting—with all the opportunities there?

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[G.J.]: Well, research assistants were only hired – first of all – for the length of the projects, so the project was 12 to 18 months, or in 18 months. So, I'm not sure I would have been hired on to the next project necessarily. But, they really were jobs for straight-out-of-college people for a couple of years to come be in Washington. Great having that congressional ID, going to the Library of Congress—you can get into lots of things. But, then their expectation was that you would move on. There wasn't a path word—a career path at that office at the time. So, I had always planned on going on to law school, but I decided to defer a year to go work in Washington. I think that was very valuable.

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[M.B.]: So, now you're at law school. Where did you go to school and what did you do while you were there? Did you focus on your future?

[G.J.]: So, I went to Harvard Law School, and I did. So, my interest again continued to be in science and technology and law. And, in particular in how law and regulations are required to change because of new science and technology, to a large extent. So, the first year I just took all the regular courses you could take as first year in the fall semester.

But, actually, in the spring semester, they had a third-year seminar, which was for students who were there last year at law school on biotechnology and the regulation of biotechnology. And it was taught by a professor by the name of Richard Stewart.

And so, I went up to him as a freshman at the beginning of my—middle of my first semester and said I want to be in your seminar. And, he said well, why? You're the first year; you're not allowed to be in these seminars. You're a freshman. The first years—we were allowed to take one elective in the spring—but there was a list of defined electives. And I said, “Well I wrote my college thesis on this topic,” and little by little I convinced him that I would be valuable to that course, and so he agreed to let me in the course.

But, then the university wouldn't let me in. The law school wouldn't let me in because I wasn't a third year. I wasn't a third year. And so, we both went and fought for that and eventually the law school allowed me to take a third year seminar as a first year with the understanding that the paper I wrote in the third

year seminar wouldn't count as my third year paper. I'd have to write an additional third-year paper. But, this was a one—once a week seminar course on biotechnology and the law, and I ended up using a lot of my thesis files and so forth. I ended up teaching a number of the classes on the biology around genetic engineering because Dick Stewart didn't really have that knowledge about it. He was learning about it.

So, I ended up writing a third-year paper in my first year, which was more of a legal analysis of my—of the topic I had done as my thesis. And, I ended up getting that published a year later in the Harvard Environmental Law Review. So, I did continue both on biotechnology, and then I also wanted to take as many courses as I could in this area of science and technology. So, while many of my classmates at Harvard Law School just take courses in the law school, you are allowed to take courses other places. And I took a science policy course at the Kennedy School of Government. I ended up taking a course on Technology Law and the Working Environment at MIT. I ended up doing a third-year seminar on health law issues.

And I ended up writing a paper on institutional care committees, which was somewhat similar to the animal care committees and some of the things I had done when I worked at OTA. And I ended up having that paper also published in the Journal of Legal Medicine—I believe it was. So, I sort of—law school helped to solidify this interest I had in technology and how technology forces laws to change, forces regulations to change.

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[M.B.]: Okay, you've experienced law school. You're done. What then? What did you do?

[G.J.]: I applied to be a clerk. I wanted to be a clerk for a year before going into the workforce. and I'm from New Jersey, so I ended up getting a clerkship at the New Jersey Supreme Court with the Associate Justice Alan Handler. And, actually, one of the reasons I picked New Jersey Supreme Court was they were one of the foremost courts in dealing with issues around technology and law. They had done the Karen Ann Quinlan decision, which was the original right to die decision around life sustaining technology.

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So, it was exciting to me to be in that court because at that time they were a very liberal court. They were one of the foremost courts in dealing with some of these science and technology issues. So, that was a way to go and, again, to continue my interest from a different perspective – this time being from the judicial perspective and from the common law perspective on how to deal with some of these technology issues in a policy environment or a legal environment.

So, I worked there for a year, and then I applied to be a trial attorney in the Justice Department. They had an honors program for entering—they don't normally hire entering lawyers, but they have an honors program that allows—that they specifically hire beginning attorneys and I applied, and I got accepted. I was one of seven attorneys accepted to the Environmental Enforcement Section.

So, the Department of Justice has a number of different divisions. One of them is in environment and natural resources, and at that time had 300-350 lawyers and they had nine divisions—nine sections excuse me, nine sections, and one of the biggest was the Environmental Enforcement Section, which did civil enforcement, really, with the primary client being the Environmental Protection Agency. And I got hired to be in that section, which is what I wanted to do—civil litigation and trying to get polluters to clean up. That's the easiest way to say that.

But, everybody had told me even if you want to go into a policy position, it's good to go after law school and be a lawyer for a few years and really solidify that legal education. And so, that's what I did. I went to the Department of Justice.

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[M.B.]: And, you didn't consider going into private industry or working for a company, or anything like that?

[G.J.]: I worked in summers for a bunch of law firms. And I enjoyed my—and most of those law firms that—I picked practices that did environmental law, and those were interesting. But, I think I'm the kind of person who learns by doing, and in law firms, you spend a number of years learning by watching. As a trial attorney in the Department of Justice, the second day I was on the job, I was out on a business trip to start settlement negotiations with a senior lawyer. and within—I went and watched one deposition on a case in Boston at New Bedford Harbor, and then the next day I had to take a deposition.

And so, I did more hands-on work in the first six months than many of my friends in law firms did in two or three years. And so I think part of it's a personality thing but I enjoyed that, and I get excited by that, and I'm not overwhelmed at all by that. So, it fit my personality to do that and have that experience.

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[M.B.]: So, did you begin to specialize in—well, what I'm really going for here is how you began to get interested in genetic engineering in agriculture? Or was this not on your radar yet? Was it part of a broader—

[G.J.]: So, all those things—genetic engineering did always involve agriculture although it was much more on the legal, regulatory side. I didn't have--I've never taken an agriculture, I've never been taking an agriculture course in my life. And, still, haven't. So, I didn't have any agriculture background, that is correct. I grew up

in New Jersey—you know the Garden State—and I didn't grow up in the Garden State part of the Garden State, so I can't say that I've ever been on a farm—which many people have done—or taken lots of courses in agriculture. But, I also did get a—this is how life sort of sometimes…things just happen.

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So, I started working at the Environmental Enforcement Section in January of 2000—January of 1990. And, low and behold, the political appointee in the Justice Department—you have the attorney general, and then you have the head of each division. [The] Environmental and Natural Resources Division has a political appointee and the person who had been appointed a month or two and they were confirmed a month or two before I started, was Dick Stewart. So, the professor I took the biotechnology and law course with my first year in law school, ended up becoming the head of the Environment and Natural Resources Division of the Department of Justice. And when he found out I was coming to the Department of Justice and he wanted to continue on the issue of biotechnology regulation and oversight, he asked me to spend about 25 percent of my time working as his special assistant working on biotechnology issues.

So, for about the first year and a half that I was at the Justice Department, I ended up spending some portion of my time working with the Assistant Attorney General Dick Stewart on biotechnology. and his role at that time was - and again, that was just luck. This office doesn't have it—doesn't have any inherent involvement generally in biotechnology regulation or oversight.

But, because he was interested in it he knew Boyden Gray, who was the White House counsel at the time in the Bush one administration, and Dan Quayle, who was the Vice President, began a competitiveness council at that time, and one of the subcommittees on the competitive counsel was biotechnology.

And so, Dick Stewart became the chairman of that subcommittee on the competitiveness council on biotechnology. and I, myself, and another gentleman, Jonathan Wiener, who is now a professor at Duke University, [we] were his two—Jonathan was his full-time assistant, and then I was this partial assistant and we both did work on biotechnology for him during that year and a half when he was in that job.

Once he left, I spent seven years at the Department of Justice, but those were the only times I spent on biotechnology or genetic engineering because it wasn't something inherent at the office, it was something that was being done because of a particular—Dick Stewart's interest and his connections.

So, in that framework, I got to be involved in a lot of the initial discussions within the White House, within the Office of Science Technology Policy within OIRA, the Office of Information Regulatory Affairs. or Regulatory Analysis. When the rules

were being established in the different agencies—for example, the rule at EPA for plant-incorporated protectants—protectives was going through the interagency process at that time when I was involved in many of the meetings and seeing first-hand how this regulatory system was being developed.

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[M.B.]: So, there was a transformation of US policy toward biotechnology in the 1980s, and '90s is I think what you're saying. How did that look from the inside? What was the major transformation?

[G.J.]: The way I always describe the history of this technology and its oversight was really in the mid 80's when they came up with a coordinated framework in 1986—which I wrote about in my legal paper but wasn't involved in.

But at that time, there was—the industry had come to the White House. I mean you had an earlier time period—the Asilomar time period when scientists were self-regulating themselves, and you had NIH setting up regulatory guidelines.

But then as products moved towards commercialization you had an industry actually coming to the White House and coming to the government saying, “Please regulate us. We want a pathway to market. We realize these may have some controversy or, for a number of different reasons, we feel it's important to have a pathway to market and what oversight we would have in that process.”

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And that was interesting because it was during an era when Ronald Reagan was president, and a time period where, at some point, he was even interested in eliminating EPA as an agency. But, here was an industry—the business coming to that White House—and saying, ”No, we want to be regulated. We don't necessarily want lots of regulation, but we do want oversight, and that's beneficial we think in the long term.”

And so, that's how the Coordinated Framework was first established. When I wrote my paper interesting [that] people don't always know Al Gore was actually very interested in this issue and he actually introduced—he was a congressman at that point from Tennessee—and he introduced legislation to give EPA authority to regulate biotechnology and genetically engineered organisms, way back when, a statute which never made it out of committee, or even a hearing, or anything like that.

But, Al Gore was very interested in climate change. He was very interested in scientific issues, and so he was actually one of the people who was introducing legislation on this issue. So, there was legislation as early as the mid ‘80's in Congress on this issue, and then you had industry coming in and establishing that Coordinated Framework, which then in the early ‘90s was then being

implemented by those agencies as products were now coming, ready to come on the market.

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[M.B.]: So, you said you spent seven years with the Justice Department and, over that period do you think your understanding—did your understanding of this regulatory framework advance and—why would you leave I guess is what I'm going for.

[G.J.]: So well so, as I said, I only spent about the first year and a half of that time with any work on biotechnology or genetic engineering and regulatory oversight. Dick Stewart left, and that fed off—that work faded, and I went back to being a full-time trial attorney in the Environmental Enforcement Section doing cases in region—EPA's Region 1 and 2, which was New England, New York, New Jersey and the Caribbean. I'll admit it was a great job. I was involved in multimillion dollar cases. I helped get some sites cleaned up. I found it interesting work. I liked working with the scientists in the agencies and the engineers helping develop the cases.

But, overall, at the time, I didn't feel I was—I wanted to be a trial attorney my whole life. I still had that inkling for interest in policy, and lawyers spend a lot of time fighting other lawyers on procedure, not on the merits. Is this pollution or is this harmful to the environment? But can I take this deposition or can I get this witness to answer this question, or can I strike these defenses? And that wasn't as interesting to me.

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So again, always you don't know where your connections are for things like that. I mentioned that the first day I started working at the Justice Department, I got hired to work with a senior—they assigned me to work with a senior attorney, Bruce Buckheit —and the next day he had a settlement negotiation with DuPont for their Chambers Works facility in New Jersey right across the—if anybody's ever traveled on the bridge from Delaware to New Jersey, Delaware Memorial Bridge, it is right there on the left as you're crossing and going north. And I went up and did that negotiation with him while he moved over to EPA and worked in the—he was hired to head the Clean Air Act Division at EPA dealing with Clean Air Act violations, and he asked me to come over as senior counsel.

So, I left the Department of Justice after seven years and came over and started working for him as the senior counsel in the Air Enforcement Division. So, becoming less - more of the in-court lawyer, and more of the developing-the-cases lawyer and being the client. And I worked there for four years doing that, which gave me insight into working at EPA. I [also] did some rulemakings that came into - so, I didn't do just litigation, but I helped develop cases—primarily the coal-fired, power-plant cases that were brought into the Carol Browner

Administration at EPA to try to get coal-fired power plants in the South and Midwest, including Duke power, was one of our big—one of our bigger cases…down here in North Carolina, as well as the Tennessee Valley Authority over in Tennessee. But, I also got to work on some rulemakings and some other things, so it gave me—I became less of a trial attorney and more of a regulatory attorney.

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[M.B.]: So, you described a training for sort of an emergence in the regulatory environments at the federal level—two different areas of that. Why did you leave government work? I assume that's what's next.

[G.J.]: Right, so in 2001 the Browner Administration was leaving and the Bush II Administration was coming in. And I loved working—I liked working for EPA, just like I liked working at the Department of Justice, and I could have easily seen myself staying at the Department of Justice. I could have seen myself staying at EPA, but I'd always wanted to get back to biotechnology, to be honest with you. So, I applied to different jobs. Whenever I'd see an advertisement, I applied to jobs that were involved in biotechnology, and one of those jobs was underneath the Project Director at the Center for Science and Public Interest. So, I blindly sent a resume to that job, and I got interviewed, and I got hired.

And so, while I loved working in the government—and I felt good about working in the government, and there were lots of advantages, and I learned a huge amount in that process—this was a job in the area of the topic [that] was always near and dear to my heart. And so, I took that opportunity and moved over to the Center for Science and Public Interest. And, I've now been there for 14 years.

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[M.B.]: Did you feel your audience or your public had changed when you went from working for EPA or the federal government directly to working for a nonprofit, nongovernmental organization?

[G.J.]: I wouldn't necessarily say the people changed. I mean, in the government or the EPA—you think you're there trying to protect the environment on behalf of all the public, all the citizens of the United States. And so, I think—I mean, it was always fun to go into the court and say I represent the United States of America. I represent the Environmental Protection Agency although less fun in the—when I went to court in the Virgin Islands where they didn't really like having too many - even though they're part of the United States, and the courts are US courts, they didn't always love having attorneys from Washington, DC, come down.

So but, overall, that was—it felt good to do that, to be part of that. And, to be helping to clean up the environment and helping doing things. I think at a public interest group like the Center for Science Public Interest they also have not an identical role, but they are there to see citizens eat well, eat healthy, make sure that industry is doing the right thing and not trying to set consumers on the wrong path…and also overseeing and being a watchdog of government to make sure they do the right thing.

And so, I thought on one level I was doing a lot of the same stuff, but clearly, I could use the experience I had in the government to help influence the government and make sure that they kept on doing the right thing. I had been on the inside seeing the impact that NGOs or industry could have, and that helped me in this new role I was, to help try to effectuate that now from the outside.

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[M.B.]: So, it's 2001, you've just started this new position in this organization. How had the climate or the regulatory concerns around genetic engineering specifically in agriculture but more generally? How had that changed since the last time you had been directly connected to biotech concerns?

[G.J.]: So, when I—again I didn't do—so I was involved in 1990, '91, '92 time period. And that was when the regulatory system was really just being established, so there weren't any products out there in the agricultural field. The Flavr Savr Tomato was to come later. So, you were sort of setting up something that hadn't been used in practice yet.

By 2000-2001, you had products out there that farmers were growing, and you also—I came in after StarLink, which completely I think changed the—a lot of the discussion…both in the regulatory agencies and in the public because there had been an instance where something that was not supposed to get into food had gotten into food, and again, I ended up learning about that historically because I was not [involved]—I would admit in that eight year time period [not] spending a lot of time following this topic. I'd read articles in the poster—newspaper about it, but I can't say I was spending all my free weekends [reading them]. I was spending them with my kids; I wasn't spending it reading about biotechnology.

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But, I think that that—so I think we had—the situation had changed. We now had tested regulations; you now had an industry that was producing products. You had farmers who were growing it, and now you had also controversy on a different level. The original controversy that came from these technologies back in the '80s was from Jeremy Rifkin, and the foundations on economic trends, and it was an anti-technology opposition.

And, some of that had religious undertones involved with that. And I think by 2000 and [after], it was a different—some of the objections were different. There

were still some objections in technology, but instead, they were now objections to big business. There were objections on scientific grounds to—how these would interact with the environment and other kinds of things, so I think that the initial discussions were more on ethics and "Should we do this? And, why are we doing this? And, how does this change relationships with nature and other kinds of things, playing God and so forth?" I think by 2001, time period I came into as more about safety environmental impacts, the role of agriculture, role of big corporations, and other things.

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[M.B.]: So, did you see your own interests and perspective on biotechnology shifting from the time you had written your thesis to the time you are re-entered the field in 2001?

[G.J.]: I don't think so. I think I still had the same overall view, which was that I think this is a technology that could be applied safely, but that it did need some oversight. And so, the question was: what does that oversight look like? And, how do you establish that?
So, I don't think if you went back and read my college thesis—I think the argument that would come out of that is that this is a technology that can be used very safely. It could also—you could develop things that would have risks, and you do need some oversight of it. The question is: what is the proper oversight, and how do you do that to reap the benefits, but also reduce the likelihood of any those risks from occurring?

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[M.B.]: So, was there a particular issue that you entered into in 2001 a particular controversy or what—how did you—what did you work on when you came in?

[G.J.]: So, I mean I re-entered the issue at that time, and so it took me awhile to get back up to speed. And, as I said, I was not really involved in the StarLink and the immediate aftermath of StarLink, which had just happened in that last year or two. So, it was a part of just establishing the project, and the project was established—to a large extent my boss had been asked to testify, Michael Jacobson, in 1999 at FDA about what kind of oversight they should have on this technology. What role should FDA be playing? And I think he—when he researched that, he realized that these things were entering the food supply, and that was sort of the mandate of CSPI. We're about food and nutrition and things that are there.

We felt this was right for us to have a project, as well as the issue of—he felt the debate was quite polarized with opponents and proponents…industry saying, "This is safe. We don't need to be regulated." Opponents saying, "This could have all kinds of doomsday environmental scenarios." and he felt both of those [groups] were not really being genuous in the facts. So instead, they were being disingenuous. and felt there was a need for a moderate consumer group that could look at this technology, look at the science, look at the policy issues and

provide fair solutions to all of those and provide good information to the press, the stakeholders, members of Congress, others, and foreign governments…so we would have a better understanding of this technology. What it's—what the good parts of it are and what are its limitations?

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And so, the role as I started as a co-director with a scientist, Doug Gurian Sherman, for about a couple years, and then he left, and I became just the sole director. But, the role really was to establish the project and to fill that middle void that really wasn't as big a part of the debate.

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[M.B.]: And, was there a particular controversy in those early years that you think is indicative or typical of the kind of work you've done? Or that allowed you to take that position, that middle ground?

[G.J.]: No, I mean I don't—I think we looked at the initial products and found that those were safe and had some benefits, but that the regulation oversight from those needed improvement, and so, we ended up coming out with a coming out article I call it in November, the issue of our Nutrition Action newsletter. The cover story was on genetically engineered crops and their oversight and their safety and everything. And that—so, we spent the first few months in the job researching and putting that together, so it would be our policy statement. And, I think a lot of the conclusions we had back then still exist today to a large extent. I don't think a lot of that has changed.

But, in particular, we focused on FDA, and it was interesting because the FDA—just before I started at CSPI and at the end of the Clinton Administration—came out with a proposed rulemaking just in January on the—if you're somebody in Washington you know that things happen at different times and a lot of things happen at the end of an administration. Right before they're leaving and one of the things they did was propose this what they called a Premarket Notification Rule, PMN, or something like that; PMN Rule that would have taken the voluntary consultation process in FDA and made it—I call it voluntary without teeth. I mean, they would have taken the voluntary process and made it "mandatory without teeth," in my opinion. But, they were trying to satisfy some industry players—the food industry who was very interested in getting FDA more involved in the oversight of these crops so that they weren't the one—solely the ones interacting with consumers about it.

But, the statute really limiting the ability, they could do so they proposed this mandatory rule which actually went nowhere because, at that point, the Bush Administration came in. And a couple years later, they made the decision that the statute didn't even support this minimum change in the regulatory climate because they were fairly strict constructionists on how to read that statute, and

they read it more narrowly because they didn't want big government. Their field was small government, and so, they tended to read things narrowly to limit what would be regulated.

And so, that rule passed by the wayside, which led the way to one of CSPIs' the topics I've been working on for 14 years still which is to have FDA have a mandatory premarket approval process at FDA so that HG—genetically engineered crop would need to get FDA's approval before it was released and [available] in the marketplace, which isn't what currently happens today.

[00:37:37]

[M.B.]: So, you've described for us the basic regulatory framework around genetic engineering in agriculture. But, I wonder if you could spell it out for us a little more clearly. Is the—what is the kind of basic arrangement in federal agencies around how a new crop is regulated—is permitted to pass into the food supply?

[G.J.]: So, really, the regulatory oversight structure that the US government has related to genetically engineered organisms—and this doesn't—is not limited to crops or animals, but would also include microorganisms that might be used for biofuels or other types of things. So, it's not limited solely to agricultural context—straight agricultural context. Was the coordinator framework, which was a document that came out of the Office of Science Technology policy back in 1996, which is an arm of the White House. And that pretty much said made a couple of large principles for oversight of regular—of genetically engineered organisms.

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One it said that the risks from genetically engineered organisms don't differ in kind from other kinds of products that are out there. So, they might differ in degree. You might have a greater or less likelihood chance of food being an allergen because it's been genetically engineered, but allergens exist independent of biotechnology or genetic engineering, so it wasn't they said there were no new kinds of risks, but that the risks might differ in degree.

And, therefore and they wanted to look at the product of the regulation should be based on the final product not necessarily based on the process that produced that product. So, we would and most of our statutes are product-based statutes. You have a pesticide law. You have a drug law. You have a food law. So, we have laws that are based on products, not based on the process. So, any food that is covered by the Food and Drug Administration, no matter how you make that food. Or, a pesticide is covered, whether it's a biological pesticide or a chemical pesticide in the pesticide law, and so forth. So, they did—they reiterated that we would look at these things based on the product itself, not the process.

So, that was the framework upon which the regulations in the early ‘90s were established. But, primarily when it came to genetically engineered crops, which were the ones—at that point, we didn't have animals in the early 1990s. The regulations were at three agencies: The US Department of Agriculture, the Environmental Protection Agency and the Food and Drug Administration. And, again, that was based on stat—existing statutes.

So, under Food and Drug Administration, for example, they have a statute called the Food and Drug, and Cosmetic Act, and that was first passed in 1906. There have been amendments to it over the years, but obviously, a statute that I think at the time—the last major amendments had been [in] 1958, [and] we didn't know about DNA in 1958. DNA hadn't established, so there's no discussion of DNA, let alone genetic engineering or genetically engineered food products.

But, it does talk about the fact that foods must be safe and not adulterated. And gives a regulatory structure to FDA to oversee the food supply…to require approval of food additives. But and in this instance, in 1992, FDA decided that they did a Flavr Savr Tomato which was the first engineered product, came in as a food additive petition. And, they had a science-advisory panel, and this was not at a time I was spending a lot of time working on this, so this was not first-hand knowledge. This was reading about it after the fact.

They decided that they didn't want these genetically engineered crops, which were really corn plus one new gene, to go through a food additive process. and they said that they were generally recognized as safe, which is an exemption to the food additive process in the law. And so [they] set up a voluntary consultation process. And, that still holds today.

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So, FDA regulates genetically engineered crops as saying they are not food additives, they are generally recognized as safe—but they do have a voluntary consultation process where developers can provide data and FDA will look at that data and give—doesn't give its opinions, so it doesn't tell the public that these are safe, or they agree with the company's assessment; they answer with a letter that says, ”We have no questions at this time about the determination that you think this food is safe. You're responsible for safe food.” So that's the exact wording that they use. “You” meaning Monsanto or DuPont, NC State, or whoever is developing that genetically engineered crop variety.

So, we have that process, which was set out in the mid-‘90s, and it pretty much has not changed at all. Again, there was this proposal in 2001 that never saw the light of day. But, otherwise, that process has kept with one minor exception where they added a process for an early food safety assessment for things at the research stage, if the company wanted to come in again voluntarily. That process hasn't changed.

But they—so, they base it on the product; they use an existing statute, and it doesn't really have, doesn't fit—I always call this the regulatory system in the US and fitting square pegs into round holes, where they're sort of putting in a process. They're fitting in a product into regulatory processes that may—that weren't really established with this product in mind, and so, there may be good and bad aspects of that. There may be gaps where things are missing, or there may be overlaps. And so, the other two agencies are the Environmental Protection Agency, and they regulate under the federal food drug—no, excuse me the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA. And, that requires that all pesticides be registered before they can be entered into commerce.

So, if you're a farmer or a rat gardener, and you want to buy a pesticide, you can't buy it unless it's been registered. And, the way that EPA regulates these biotech crops is many of those crops are—well I'll give you the example of the BT crops—ones that have Bt pesticidal and gentis genes introduced to them. They're introducing a toxin that kills the pest, and a pesticide is defined as anything that kills a pest. It could be a synthetic chemical. It could be a biological substance. It could even be an inert substance like iron that might kill a pest. And, anything that kills a pest is a pesticide if you intend it to be used to kill that pest. There's an intent portion of the statute just like under the Food, Drug, and Cosmetic Act—food is something you intend to be eating. If you want to use it for a different purpose, even if it could be eaten, it's not considered food. It's whether you intend it to be eaten.

Similarly, a pesticide—if you intend it to be used to kill a pest—then it has to be registered, and so the BT crops that were developed by Monsanto and others…BT corn and BT cotton are intended to kill a pest. And so, FDA—EPA decided that those needed to be registered under the Federal Fungicide, Insecticide, and Rodenticide Act. And so, they set up a regulatory process, and they called these plant-incorporated protectants, PIPS, because they incorporate the pesticide into the plant, and it's produced in the plant. In this case, the bug eats a portion of the plant where that is produced. It might be the root for rootworm; it might be the leaves for corn borers or the—and then the pest dies, and they don't—the scientists and the farmer doesn't need to apply another pesticide biological or chemical, or synthetic pesticide instead.

So, they set up a regulatory process to do that, and so, a subset of all genetically engineered crops get regulated by EPA under that process. And that, I think, is a very thorough process. It does have a fair amount of transparency and public participation. EPA has a history [of being] primarily a regulatory agency. That's its job to regulate industries, whether they're Clean Air Act permits or water discharge permits. Their job is not to promote any industry; it's to—well, that's not true. They may promote solar power and other kinds of clean energy, but

they're not sending out grants. The Department of Energy would do that. Their role really is to protect the environment on behalf of our citizens.

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And so, their analysis is public. The public gets a chance to comment, and one of my jobs at CSPI is to provide comments to the agencies, and I do that on EPA very regularly. I go through rules and their individual applications, or individual permit registration requirements. And their statute is more of a balancing statute, so they look at both the benefits and the risks and say, ”Is this pesticide safe for the environment? And, will it have benefits?” And so, they approve these products. So that's a different regulatory process.

And then the third regulatory process is the US Department of Agriculture. And they decided again back in the early ‘90s that they would regulate genetically engineered crops as potential plant pests. So, at that point, there was a Plant Protection Act. No, excuse me, there was a plant pesticide—there was—I can't remember what it was called. Plant, plant, Plant Pest Protection Act. But, there was—they had legislation, they had authority to regulate plant pests which are things that could harm agriculture.

So, you might think about kudzu—it’s a plant—is a—would be something that harms agriculture. It's growing all over the place. It's a weedy species but also different kinds of viruses. So, you might have a virus that kills papaya plants that would be a plant pest, and their [USDA] job is to regulate those to prevent those from having agriculture impacts.

Well, they decided that genetically engineered crops—if you added a new gene and one of the main methods of adding that gene into the plant was using agrobacterium. An agrobacterium is a listed plant pest. An agrobacterium infects plants, and in fact, that's why scientists are using it to do their transformation because they could put the gene on a plasmid in the agrobacterium and let the agrobacterium do its work. It would infect the plant, and it would take the DNA into the plant, including that little bit of DNA that the scientist was trying to get in that had that new transgene.

And so, USDA said, ”Well if you're using agrobacterium—if you're using portions of plant pests—in your process, who is to say that this corn now doesn't have plant pest characteristics? So, we're going to regulate it.” The other reason they did that was a lot of the promoter sequences the initial promoter sequence that the portion of the cassette of DNA that's introduced into the plant. That is—that turns the gene on. Well, in many instances they use the cauliflower—a promoter from cauliflower mosaic virus. And, the cauliflower mosaic virus is also, again, a named plant pest, so there was another portion of a plant pest that was used in the process.

So, they said that they needed to be regulated, and you would have to get permits when you do field trials, and eventually, you would file a petition for nonregulated status. You would get that plant deregulated when you could show to them that, in fact, the corn or the cotton plant with the new gene is interested—is introduced into it was not any more of a plant pest than the conventional plant, conventional corn that didn't have that gene introduced into it. And so, that's how they started their regulatory process.

And, why I call this process has got some ambiguities, and so you could have a BT corn that would have both oversight at USDA and oversight at EPA, and it would have the voluntary consultation at FDA. But, you might also have crops if it was an herbicide-tolerant crop those don't get regulated at EPA. They only get regulated in USDA.

Again, if it was a food crop, you might go through the voluntary consultation so you could—so you would have a diagram or some products have three oversights; some got no, one oversight, or two oversights, depending on the technique that was used. and today we now have genetically engineered crops that don't use any plant pests in them, Like the Kentucky bluegrass that Scotts is developing and getting no agencies oversights.

So, the system I called have gaps and square pegs into round holes because, in some cases, by picking old statutes and applying them to new technology in some places, you over regulate, and some places you may under regulate based on that.

[00:50:22]

[Alison Wynn]: How if you—if you were able to have complete control over these processes at, say, the FDA, the EPA, the USDA, how would you change this system to make it not have as many gaps?

[00:50:35]

[G.J.]: Well, the one thing I want—the last thing I just want to mention of the regulatory system when EPA does its overview it also does a food-safety analysis. So, when a pesticide is used, we want to make sure that any food products that come from the crop—whether pesticides have been used—that it doesn't have any residues that would be harmful. So, they do take some look at a mandatory level at the food safety. But, they're looking at residues of the pests—pesticide in the food crop.

But, again so in some instances, that would be overlapping with what FDA does; and in some instances, it wouldn't be overlapping because they might not come to FDA at all. But, I mean so I think if I was doing it over again, I first would have a mandatory approval process at FDA. I do think that it's important that FDA take an independent look at these genetically engineered crops and determine their

safety and give that opinion to the public, and that's still what I advocate today. And I've been doing a lot in the recent weeks and months in 2015 on this particular topic.

I'm not sure I ever supported Al Gore's of giving—I think—if there was an agency that would be best to oversee all of this—I think EPA would be the agency. And so, maybe Al Gore's original legislation might have been good to pass. I think there are advantages to having a in-one-door in policy, and then take stuff that an agency needs additional expertise to look to other agencies for that expertise within their thing. They are definitely problematic aspects of three agencies and not having expertise, and so forth. So, I think there are ways you could do that.

I think I'm most comfortable with the EPA process. I think that's the most science-based and I think that one works the best. I think the—if I—the agency I would change the most is USDA. I think they should—I mean I think there's somebody who should be in analyzing and taking a look at environmental, agricultural risks from genetically engineered crops before they go into the marketplace. I don't think the plant-pest process is a scientifically valid one. I've always said from the beginning that just because you add a gene with agrobacterium material doesn't make corn a plant pest, and I don't think any scientist would ever believe it would. So, they used a fiction to start a regulatory system, and I think the industry liked it because they wanted some oversight and predictability. And, some of the NGO's liked it because it was better than nothing. The alternative they said this is bad and there wasn't going to be anything. But I think nobody really thinks—I think everybody now thinks that they spent a lot of time analyzing pet plant-pest risks, which, I think, most scientists would say really don't exist. Instead of analyzing real risks like resistant weeds, or resistant pests, or other harms in the ecological environment of agriculture that would actually—we could actually do something about. And so, I think that's what's missing in the system.

[00:53:34]

[M.B.]: To what extent do you think the histories of these three agencies that have responsibility for biotech in agriculture—broadly speaking—to what extent do you think that their histories play into their efficacy or the problems you just described?

[G.J.]: Well I think you know I've learned— one of the things that I have learned is that each agency has its own little ethos or its own philosophies, or it's just the way it works and the way it interacts and way oversees. EPA was primarily set up—I forget when the statute was…in the ‘70s or something—to be for the public interest, to protect the environment for the general interest so they're not a promoter of any one industry. They're really a regulator of a number of industries, and so, they have a arm's length in general—this is a very big generality—they have an arm's length relationship with the industries that they regulate. Although, when I worked there for a number of years, I would have

said that there's part of—some industries that are captured part of the Air Office and things like that. Overall, they have an arm's length role that is to regulate and oversee and to issue permits, and sort of always be the bad guy, as somebody might say from the industry side.

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But, therefore and built into a lot of their statutes is public participation is transparency, and many of their statutes are balancing statutes. We balance benefits and risks because the environment is constantly changing, so it's not about what is ideal, but is this better than what we have? Is this going to take us in the right direction? Let's say for pesticide a more sustainable system something along those lines in the broadest terms.

Other agencies, like USDA, is a big promoter, and this was actually written in my back in my law review—back in my law school days, I wrote about the fact that FDA was both a—I mean USDA was both a promoter I mean they're there to promote agriculture. They promote it internationally. They give lots of research dollars. They're there for farmers. And, at the same time, though, they do have a fair number of offices that do regulations. Safety oversight, whether that's oversight of food that comes from those animals, be it animal safety—they have USDA inspectors at meat plants every day before they start working to make sure that they're safe. So, they're regulating food safety. Or, whether they're regulating biotechnology or plant pests or something like that.

But, with that in mind, because they still, in the end, are all part of that organization they also have some conflicts of interest in the sense that well they—if there is something—if some industry does really detrimental things, they don't want to hurt US agriculture's exports at the same time. So, they may temper how they say that, or how they deal with that, which may or may not be in the best public interest of the consumer or the public. So, they may be less transparent, or they might not have been subject to as much transparency, as an EPA was, for example.

And so, I think it's taking them a long—a little longer to get used to [that] in a topic like genetic engineering, where there's lots of public interest and lots of public debate. Setting up a regulatory system that is transparent and participatory…I think they've now done that. But that took them a while, learning curve to figure out how to do that. FDA is an agency as I said, they don't—generally - they're an agency that doesn't like to go further than whatever Congress has mandated them in their statute.

So, they have this voluntary consultation process and others, again, as I said, might read that more broadly to try to make it more mandatory or something, but generally, they don't want to do that. They are hesitant to make changes without Congress requiring them to make changes.

And, they look at their regulated communities somewhat differently. In some instances, they look at it—in the drug area, it's a proponent of the drug, and they work many of their regulations and their data collection is—they work jointly with the companies to figure out what data is needed for an animal drug or a human drug, and how to get it through the safety process. So, they think of themselves as a facilitator, to some extent, in addition to being a regulator. Whereas EPA, for example, doesn't much more at arm's length in how they work with the industry.

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[M.B,]: So, you described a regulatory structure based on enabling legislation in these three fundamental federal agencies. But, you moved from those agencies into this other position with CSPI. What role do you think CSPI plays in regulation, or what is your effort in these 14 years to move the regulatory structure?

[G.J.]: So, I think what we—what I've tried to do, and what I think CSPI has tried to do is make sure we have as good a regulatory system as possible. And, parts of that—some of the characteristics of that system are the transparent, system so we—the public knows what—who's making the decision, what the decision is, and what's the basis for that decision. as well as public participation. The opportunity to give a comment of an academic [institution], or places like CSPI, where we have lots of expertise, to provide a comment on missing information that the agency may not have in front of them to make the decision, or a different way to look at some of the information that they have in front of them. A different way to analyze it to make a different decision. I think we look at the role is to make sure that we have a good—there is a robust regulatory system at the agencies—to make sure that to the extent that [if] there are any risks, that those can be caught by the agency and not let out into the environment or into our food supply. And, that sometimes entails, as I said, writing comments, working with scientists, trying to meet with the regulators, provide ideas, and be a check and balance. I mean, we are there as a watchdog of, not just the industry, but of government, to make sure the government basically makes the decisions—make good, science-based decisions that are defensible.

[00:59:41]

[M.B.]: So, one of the phenomena of working in the public arena is that you—it's possible to make enemies in surprising places. And, I say that because, to my surprise, it looks like there are people out there who think that CSPI is taking too lenient a line with the agencies…that there are people who actually think that your group should be even more aggressive in fighting against industry, for example. Where I'm going with this is: do you feel your group has found surprising opposition or dislike from people who are advocating against genetic engineering in food?

[01:00:33}

[G.J.]: So, while I like working at CSPI, as I think that we're both science based, so we do look at the science to help us make our policy positions and our decisions. And so, that's where the heart of what we say comes from. And, I think that becomes more defensible because it is the science.

At the same time, we also believe that a little change can be really valuable. So, we petitioned—I'll give an example of a topic I don't work on but trans-fat so we petitioned FDA back in 1995 I think was the date when we sent a petition to FDA to regulate the label—require labeling of trans fat because of its health problems. And, it took about 12 years for the agency to grant that petition, or to establish trans-fat. And, we were the first ones to do it, but then we had to make a broader coalition of doctors, of other people and scientists, and others, who came on board over those years and put pressure on the agency and others, so that the position now became a position that FDA—there was enough evidence and data so that FDA had to do that.

Now we're in the process of FDA trying to eliminate trans-fat, and the companies are trying to come in and identify places where they still need trans-fat. So, it's becoming—they've suggested that trans-fat will be a food additive, and you only will be allowed in certain areas where they—that's the only option for producing that particular food…again, to continue limiting it.

So, we might have originally gone for elimination of it, but we felt that that was not the best way to go was to first get it labeled. And you move a process down the line, and you may achieve your end goal later, but you may achieve milestone goals in between that of real benefit.

And I think—so, we look at a lot of different issues in that context; and while I might say that it would be great to make—grow all of our corn sustainably, whether that was with organic methods or other kinds of integrated pest management and weed management methods, and so forth and so on. What I can tell you for sure is that growing—using some genetically engineered crops is a little better for the environment than using some of the older conventional techniques that they replaced. And so, that's a positive thing. And, I think that we believe that baby step in the right direction is something we want to support and move from there while there are many other organizations who might say, ”Well, we only want to support that final end getting the brass ring.”

But, our view is that's not realistic, and so that may be idealistic, and it may be good, but I think we're practical, and we feel that we're going to try our best to move us in the right direction on what we eat, on how our food is made, on our nutrition, even if those are small baby steps and I can't say that every group has that same philosophy. I think that we have. But that's one of the reasons I like working there is because they have that philosophy of that—of doing it that way.

[1:03:43]

[M.B.]: So, one interesting thing about the science around lab technology and genetic engineering more specifically is how fast it's moving. It seems like there's a new tool a fundamental shift, or what might become an important shift. And, here, I'm thinking of things like CRISPR, for example, which really has only appeared in the public eye since I began—we began doing this archive.

Is there—has that fact of constant emerging technologies in this area—has that had any impacts in the way that your work has occurred at CSPI and before that? Is the constant arrival of new science basically shifting the perspectives, or the work that you do?

[01:04:35]

[G.J.]: So I think I mean I think it's great that we have new technologies all the time, and I think we'd be excited about adopting them if they had benefits and they don't have significant risks. I think the issue is to analyze that and to make sure that the regulators or the scientific community catches up with the industry. So, industry people may always be moving very quickly. And one of the issues is that government tends not to have as many scientists on the cutting edge, and so they end up playing catch up.

And so, for us, it's not that we're against any of those technologies and in fact, they may be safe and may be extremely beneficial, and in that case, we will end up supporting them. But, we want to make sure that they aren't going to also expose the consumer to risks at the same time or the environment to unnecessary risks.

And so, I think there's always going to be that balance of making sure that technology doesn't go too fast—so that there's an opportunity for regulators and others to catch up and figure out to answer the first question. The first question is: what's the risk profile of this technology or its applications, and therefore too does it need to be regulated or not? But, one of the exciting things about my job is you're always looking at—me more than others at CSPI will be looking at some of these new technologies and how they move towards the marketplace.

[1:05:53]

[M.B.]: So, we've talked about—you've talked about regulatory agencies, about industry—and there's another group, of course, who's also doing a lot of research in these new technologies—and that's universities. And, I wonder what relationship you've had with the university personnel, or with universities more broadly in your career.

[G.J.]: So I mean I think universities have great scientists who do really good work out there. And, what I like—I think my role has always been to try to take that good work and apply it, and translate it into public policy, or translate that research in a

way that can be utilized by people in government. Or people establishing public policy to the best way possible.

So, I've tended to work with scientists in different fields, like entomology or weed science, when I wanted to get opinions about problems that are out that have arisen because of genetically engineered crops and what our potential solutions to those, and what's the evidence supporting either those solutions or those problems. And look to academics, who do lots of very good, independent research. to rely upon both to understand the problems, but also to be a check on government's proposals on how to solve some of those problems. Because they can look at those and say, ”Well, those are realistic,” or whether they're misrepresenting the science or changing the weight of the evidence.

So, I find them extremely valuable, and I like to work with academics as much as possible who have worked in these—the areas that are relevant.

[01:07:36]

[M.B.]: So, academics in universities are interesting because sometimes they have purely analytical interest in these technologies. Other times, they're actually working in the labs to create some of these new tools. And, there may—they may be spinning off companies or getting patents that end up—they may move into industry from there, or work closely with industry. How does that—does that tension show up in their advice they give you? Are academics willing to admit their perspective, or do you have to supply that?

[G.J.]: So, when I first started at CSPI, we had a conflict of interest science-conflict-of-interest project, that really dealt with the fact that it was important that scientists explain their conflicts of interest and where they got their funding from. We feel that—and I think on the whole—that's a good principle. that it's important to know where people are getting the funding for the research that they're doing.

But, at the same time, at CSPI, we don't eliminate research just because somebody's gotten industry funding for that research. We're still going to look at that research and see is this good scientific method? Did they make a good analysis? Did they have good data? Did they come to good conclusions? And, that can happen with an industry-funded study, as well as publicly-funded study. It's important to know if there is any biased or potential conflict of interest in there to be able to factor that in, or realize that the question may or may not have been said differently—looked at differently, the research question because of that.

But, I—we don't, and I think as a personal matter, that I wouldn't—I don't think you eliminate good research just because it was funded by industry. But, I think it's a piece of information that's useful to have and needed to have to be able to independently look at that study and judge its merit and its worth.

So, I've used academics who have gotten industry funding. And, I find some academics who have gotten industry funding, may be the biggest critics of industry. I'll give you the example of Aaron Gassman, who is a young researcher at Iowa State entomologist. And I asked him, and he gets funding from industry, and he says that we at the university, every entomologist gets some funding from the industry.

But, he's the one who found field resistance to BT corn rootworm out there and he's the one who's been advocating a—he designed a test, which is not particularly liked by industry to define what a pest is, in fact, resistant to BT corn rootworm which is now being adopted I think by EPA as opposed to the industry test and yet he gets funded by industry. And so, here's somebody who's funded by industry for some of his research, and yet, he's extremely critical, and he's talked about all the problems that have been happening because of their particular products.

So, I don't think you—just because you're funded by industry, doesn't necessarily mean that you're going to be somebody who's locked up with industry, or a mouthpiece for industry. I think you have to look at it much more individually than that, and so, I tend to look that way. and as I said, I've found many very valuable scientists at the ag schools and just at the universities in the United States, both public and private—that one can rely upon for good advice, and one that, I hope, also will be helpful to the regulators as they come up with policy decisions.

[01:11:04]

[M.B.]: So, the example you just gave raises a broader question. And, that has to do with science itself. It seems like the example you just gave of Aaron Gassman's work suggests that science can lead to surprising conclusions. If you set out and you do experiments, you don't know exactly what will result, and that is one of the great advantages, of course, of science as a tool is that, it can advise information, which can be useful in ways that are unexpected.

At the same time, there's a lot of discussion in society now about scientific ignorance and the broader public. Polling data suggests that the public is occasionally deeply confused about fundamental science or sometimes resistant to fundamental science. Are you—I wonder if you would speak to that more broadly in your position, as someone at a group that presents—uses science to form to create better policy, but which is also communicating in the form of your newsletter to thousands of people on a regular basis.

[G.J.]: So I mean I'm not exactly sure how to answer your question, but I would say one of the things I advocate is for scientists to communicate to the public about their science. I think especially public researchers and people who are being funded

by public funds need to see that that be a part of their job. Not just to communicate among their peers, but also to explain that research in a broader context. And, I think that you're seeing that now with more funders foundations and others who are building in a communications component to many research grants now that didn't exist ten or 20 years ago.

So, I think that is critical. I think there's a big emphasis on STEM in the schools and getting our students to be more knowledgeable about science and math. I think that's a good thing.

[01:13:01]

But, we do have a lot of scientific illiteracy in our country. And, I think it's—and therefore when you get to these areas of genetic engineering or areas of agriculture or things like that, people don't know the context around something to put it in. So a new technology comes along, and it's not put in a context because they don't know what else has been out there—what scientists have been doing independent of that for decades or for years before that. So I think we think, and our newsletter that we make a good effort to take the latest science about food and nutrition and I don't do this, so I can tell you about it freely.

We have great writers and great scientists on our staff of our newsletter who can take the cutting-edge diet or the cutting-edge research on different healthy oils, and put it out there in a form that both is educational to consumers. Useful, meaning it can actually be put into practice, and yet, stays true to the science. But I think that that's not commonplace, but we have the art—we have writers who have the art of doing that and scientists who have the art of doing that. But, that's not the norm necessarily. And, I think that is the norm we want to shoot for.

[1:14:14]

[M.B.]: Well, I want to ask you a few questions about the future, but before I do, I'd like to ask if Alison or Brad has any further questions they wanted to ask.

[Brad Herring]: Well, you kind of stole mine, but mine was: what role does or moving forward what role should the public have in regulating—in helping to regulate these technologies? The voices of non-government organizations, government organizations, and policy makers are all there. But how—I mean, you just talked about how we get the public involved, but how do we get the policy makers and government officials and NGOs to listen to the public I guess. Or should they have a voice?

[G.J.]: So, I think transparency is good, and I think it's important for the public to understand how government operates, how regulation operates, how we make decisions about science—science decisions and decisions about products, and decisions about risk. And so, it's good to have transparency. I think that's

critical, and I think the internet shows us that and everything else. The question always is in transparency is making sure you have good information. There's a lot of bad information out there also.

But also so, when I think in going with that is public participation. The ability for the public to have relevant information to really put that information out there and to help, so we can have better decisions by government and better decisions by industry, and other people out there about the products that may be on the market and the safety of them and those type of things. So, I think those are important principles.

[01:15:51]

With that in mind, I'm not I guess for regulatory decisions that are based on—I think it's important for the integrity of agencies that they make—if they're mandated—to make a science-based decision they need to make that based on the science. That is not an opinion poll of what consumers may or may not want. If there's a—if consumers don't want something, I think then or feel differently about something for a non-scientific reason. I think there's other—I think there should be other avenues to deal with that. That might be Congress. So, we might outlaw stem cell research, for example, because we say we don't want to go there ethically or religiously. It's not a science-based decision—that's a political, philosophical decision. And, I don't have a problem, if we as a society we decide to make those decisions.

But, I think for the integrity of oversight and regulation[of] the government, it's important to separate that that's not a science-based decision. That's a different decision, and if you—that it's important that we keep our science-based decisions science, so that the public can see that the basis on which we are making those decisions and the evidence for those decisions from other decisions, which may be very important policies and be very important to a product or an industry going forward. But, there may not other—may be very important values or other considerations that are based on that.

Where I see problems, is when those two come together—and what the public doesn't know whether a decision was made based on the science or based on some other factor, in which case, then they lose some confidence in the system, and the system I think loses integrity because people can't understand what is the basis for that decision and where did it come from.

So, I don't know if I've answered your question or not, but I think that government is there to help the people as a whole. And, it's there to ensure products are safe, and do a host of other kinds of roles that the market doesn't well, or other things that are needed for a civil society to exist. I think now more than ever, we need to be transparent and participatory in those processes, and take in opinions, take in viewpoints. But, I still think when it comes to making decisions,

we have to separate things that are science decisions versus things that are nonscience decisions.

[B.H.]: Yeah, I think it's just hard in today's society, when the science is kind of almost being attacked, but it's being taken out of the media, science writers are no longer around. So, really, to strive for more public participation in science is—or citizen science and working. Like you said earlier, getting scientists out in front of the public.

[G.J.]: And, I think I mean in the agricultural context, we're no longer in a growing society. Most people don't live on farms, and we actually, most people live very far away from farms. But, farmers' markets are an opportunity for people to engage with farmers, learn about how their food got to where it was. Look at an apple that doesn't look perfectly round and symmetrical without any holes or anything, and still eat it and taste it, and it tastes great.

So, I think I've always said in the agricultural space, we need a huge amount of education of the public because I think people don't know where their food comes from and what it takes to produce their food. And, I think learning that, we'll be able to put many of these technologies and industries in a better context. Whether that's science education or non-science education, however you call that, I think that's important.

[01:19:40]

[A.W.]: On a very different note, what would you say motivates you? What gets you out of bed in the morning? I think through a lot of your history, it's obvious that you're very driven. I mean, you wanted to take a third-year course your first year of law school. You applied to some ambitious positions right out of law school and right out of undergrad. So, what motivates you?

[G.J.]: I think a lot about how one wants to have influence in society, or what somebody wants to do in their job. You spend a lot of time in your job. Other than sleeping, maybe you spend more time in your job than virtually anything else you do in your life. And, I wanted to be a lawyer, so I could make some change. And positive change. And I thought that was a way I could do that.

Some people might want to become a bench scientist, but I didn't want that interaction. I wanted—to me, that was a narrower interaction with less people, but you can be very beneficial. You can find a cure for cancer or something like that, so I'm not trying to denigrate anybody who is a bench scientist or Ph.D. scientist. That just wasn't my choice. I wanted to be more engaged with people and policy.

And, when I became a lawyer, I sort of thought about also you could be lots of different kinds of lawyers. You could be a criminal defense lawyer and get

somebody off from going to prison. And if somebody was innocent and that could be a really—you could change somebody's life an individual's life tremendously by doing that. And, if that gets you a lot of satisfaction, then that's the kind of job you should do.

I decided that, for me, the place I wanted to make change or be involved in with these broader societal changes. So and that to me gives me satisfaction when I can get one of those achieved. When I can make some change.

In this job, a change in the regulations that may get more farmers to comply with refuge requirements, which would mean that the environment has some benefit. Or, when I was working at the Department of Justice as a lawyer, and I cleaned up—helped clean up New Bedford Harbor that will have lots of benefits to people around them. They don't know me, so someone's not patting me on the back, but I have that satisfaction that in fact I've had an impact on some part of our environment in a positive way.

So I think for each—I tell people—people come to me and ask, ”Should I be a lawyer? What kind of lawyer should I be?” I say, ”One of the things you need to think about it is: how do you want to interact with others in society in your job? And depending on how you want to do that, you might pick the kind of lawyer you are, or the kind of profession you might be.” I like this interaction with policy and those kind of broadly changing and debate and how that may impact in a much broader societal sense.

[1:22:38]

[M.B.]: Well, I want to ask you about what you think our—the biggest emerging issues in the general area of genetic engineering and agriculture and, particularly given your perspective from a regulatory perspective. What do you think is coming next, or is on the horizon?

[01:23:01]

[G.J.]: So I think—so I can answer that question both narrowly and broadly, I guess. I think there are a couple of things. To a large extent, all the genetic engineered crops that we have today have really been homegrown…. And what I mean by homegrown, meaning most of them either started in US laboratories, or they were even growing here in US farms first, and then they've been exported. So, the genetically engineered crops that are being grown primarily in Brazil or Argentina are varieties that were developed here. The ones that are grown in South Africa were developed here. The BT cotton grown in India is pretty much the same as the cotton that we've grown here—the gene is and so forth. So, I think that we've been the center of genetic engineering products.

I know that's going to change in the future. I think China has a lot of research in this area. They're developing products. Bangladesh is starting to grow BT

eggplant, which is now being proposed for the Philippines and for India. And so, you're going to see not the center of biotech necessarily change, but we are going to see products that are both produced in the public more, and public sector arenas has less—in addition to the private sector, which is where most of the products have come to-date, as well as things that are grown or produced outside the US. And, I think that's a positive thing. It shows the maturing of the technology and the ability to use it in other contexts. So, I think that's one trend I think one we will see.

A second thing I think we'll see is that most of the crops to-date have really been crops for animal feed. They have not really been for other industrial purposes. They really haven't been or highly refined products, like sugar beets for sugar. They haven't been things that are fruits and vegetables, or things that are immediately consumed by consumers.

But, recently we have, the genetically engineered apple has been approved, and the genetically engineered potato has been approved, and I think there [are] other things in the eggplants in Bangladesh and maybe in the Philippines, the rice in China or India or the Philippines or Vietnam you're going to see products that are now primarily food crops.

And so, I think that will change some of the debate and some of the issues around this. But, also may seem more benefits closer to consumers but less just solely for the producers but also maybe for the end consumers. Seeing some benefits. So I think that's a second trend.

And a third trend I think is we're now seeing what you mentioned—CRISPR technologies and things that are gene silencing and gene splicing. And so, we're seeing a new generation of products that necessarily won't be transgenic, but will be manipulated in the laboratory to use DNA already within the gene of an organism to change characteristics.

[01:26:01]

And so, I think you will see products like that come to market. And, that will raise different regulatory issues about should it be regulated or not. So, to me, those are some trends that I see coming out in the near future.

[1:26:13]

[B.H.]: Can I ask a follow-up question? So, you have what sounds like an amazing foothold in the regulations here in the United States, and you know a lot about that, but are you concerned about regulations from China and Vietnam and Bangladesh with regards to some of the new crops that they're creating? Is there a need for some type of a global community of regulators? Do you care to speak to that at all, thinking about the future?

[G.J.]: I mean I think so we do have international agreements and different international documents that oversee some of the oversight. We have the Cartagena Biosafety Protocol which deals with the environmental side of ensuring that there aren't risks from transboundary movement, or genetically engineered organisms going from one country to the other. But, it also it really forms the basis for at domestic regulation of genetically engineered crops in many countries. And, that's why I spend about a third of my time in developing countries helping them implement that Cartagena Protocol.

So, I think there are some things and on the food side—you have Codex Alimentarius, which has a number of documents that are consensus documents of how one goes about a risk assessment for a genetically engineered plant or animal, or microorganism that will be used with food. And what are the kinds of tests and, what are the issues that might be raised on food safety and how to address those?

So, I think there's broadly, there is a framework for how to do this. Obviously, different countries may do it better than other countries. I don't study China, and I've never been to China. So, I can't really talk about the Chinese system, and how well they will or will not regulate these products.

But, other countries, I think I have—I think - Vietnam I've been working with Vietnam, and they have set up a regulatory system. I think it's a realistic one, and I haven't delved into the details of how they've made their decisions, but the procedures they've put in place seem to be a realistic way to ensure these are safe but also beneficial to farmers. and they get out there, so I think they've probably done a decent job.

[1:28:16]

[M.B.]: I want to ask you a paired question, also about the future, but this is more about your hopes and your anxieties. What are your greatest concerns about the coming decades, years, or decades in genetic engineering, particularly in agriculture?

[G.J.]: Well, I guess one of my fears is that—there's a lot of debate around this technology, and I think there are a lot of countries and individuals that are against this technology. When I'm not sure that's really based on a scientific—there's not a scientific basis for that, and so I do think this is a safe technology that could be applied safely in many, many instances. And, we'll have products that may have benefits. And I worry sometimes that we won't get to utilize and achieve those benefits because of the debate around these products. Some of which—to the extent that people have different viewpoints, for other reasons ethical or others that I'm not going to really comment and get involved in those.

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And, those aren't—don't get me wrong, they're very important, but, I'd hate for people to make wrong decisions because they don't have a good awareness of the science, and then so they may think something is unsafe, when in fact, it isn't unsafe. So or may think something is—so I think to me that is one of my concerns is that we won't—to the extent that this has benefits, applications of it have benefits that we won't achieve or realize those benefits in places where they could really be helpful.

[1:29:54]

[M.B.]: And, what about the flip side of that? I mean, if you had hopes for this technology in coming years, what would those be? Your greatest hopes.

[G.J.]: Again, I've worked primarily in the agricultural context, not in the medical or other context, but in that agricultural context—I mean, agriculture is a very detrimental activity on the environment. You know humans have been doing it since they've been on this—for more time than I can even begin to think about. And, to the extent that we can—this can play a role in us doing that in a more sustainable manner, I think that's a positive thing. And so, I want to—I'm hoping that we can look at it in that context…as one tool in a toolbox of many that we can move our whole food system to a more sustainable and healthier food supply.

[1:30:54]

[M.B.]: Well I have one last question, but first I'd like to offer Alison or Brad the chance if they've got questions pending.

Okay, well the last question's a pretty simple one, and it's: are there any questions you expected me to ask but didn't? Or, any I should have asked but didn't?

[G.J.]: So, I'm not sure I knew what to expect, so I can't say, "Oh, I expected him to ask me this question or that question," to be honest with you.

[M.B.]: Was there a topic you wanted to discuss with us and didn't get a chance to because we didn't ask the question?

[G.J.]: I don't think so. I mean I think we've covered a good—some of the history of the issue, history of how I got involved in the issue, some of the oversight. We only talked about the crafts but not the animals, but I don't know if that's needed or anything. So, I think you did a good job.

[1:31:52]

[B.H.]: I think one question we do tend to end on is another if you enjoyed this experience, are there others that you would recommend that we would interview? It may not be that we have the opportunity to interview them, but in thinking about telling the whole story of this field, are there colleagues of yours that we should think about?

[G.J.]: Well, I think I've mentioned at breakfast this morning to Matt, a few of these people, but I think that one people that you are missing and haven't talked about are regulators. The people who were involved in setting these regulatory systems and I mentioned Linda Fisher, who was the Assistant Administrator of Chemical and Toxic Substances at EPA, when EPA was doing the PIP rule in the '90's. who is currently a Vice President at DuPont Pioneer.

Similarly, Terry Medley, one of her colleagues, was very influential in setting up and he was the first one to run the biotech shop at USDA in APHIS. Both of them, I think, would provide lots of information about the perspective of how these rules were originally established, what was the goals of those, what went on in those discussions.

Similarly, people like Elizabeth Milewski who is at EPA would be somebody else who is currently still at the agency, who has been there working on biotech issues for 30 some odd years. So, I think that perspective based on what Matt had told me earlier some of the people that I think you haven't talked to that I think would probably be accessible to speak to and would provide a very nice historical context of things, although, they are currently not spending a lot of time in the debate today. Or, this issue today. They were very critical people.

I mentioned John Corson from OSTP, who was very involved, in those days also around the establishing of Coordinated Framework and the original rules that were established at the different agencies. So, I think those are some of the people who I think—people who have thought a lot about how do you regulate this technology. How did you bring this technology to market? I mentioned others, like Bob Goodman, who is the current Dean at Rutgers Ag School, but I get in trouble for calling it that. It's Environmental Studies and something else. It was originally the—it's become a college. He was at the University of Wisconsin beforehand and has done research in this area, and I think he was actually involved in Calgene when they first did the tomato and some of the first biotech stuff. And he is very thoughtful on this subject. I think he is a very interesting person to talk to. I'm sure I could come up with other names, but those were some off the top of the head.

[M.B.]: Great. Thank you, Greg, for this time with us. We appreciate it.

[G.J.]: Okay.

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