

**REMARKS ON REGULATING GENETICALLY MODIFIED
FOODS IN THE UNITED STATES**

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{1} Thank you. I'm glad to be here today. Before I launch into my prepared remarks, I do want to correct a couple of things that Greg has just told you. Just for full disclosure, Greg and I shared an office about eighteen years ago when we both worked for the Congressional Office of Technology Assessment. When I arrived in Washington, I spent five years working as an analyst on these sorts of issues. So as I'm about to pound on Greg for knowing a number of things that don't happen to be true, please be aware that I'm not really being as mean to him as it looks.

{2} Mr. Jaffe cited a couple of problems with the regulatory system, one of them saying that field trials of transgenic crops do not all require environmental assessment and that a vast majority of them go without that. This is categorically false. I invite folks not to believe anything I say but check it out with other impartial sources. If you go to the Code of Federal Regulations, Part 7, Paragraph 340, you will find it very clearly laid out therein that each and every field trail conducted either under permit or notification for a transgenic crop reviewed by APHIS must be accompanied by a site specific environmental assessment. Those that have gone forward under the notification provision have gone forward under a generic assessment developed on the basis of vast prior experience. Each and everyone is linked to a clear and documented, NEPA compliant environmental assessment.

{3} Greg also mentioned that once something has been granted a petition for determination for regulatory status and removed from further regulatory oversight by APHIS that there remains no hook by which USDA could come back and make change to that deregulation status or so forth because they don't have the authority. This is also categorically incorrect. If you look at the regulations relating to those petitions, you will find that APHIS retains full authority in the face of any new data or new information pertaining to the environmental safety or otherwise of these transgenic crops, to revisit their determination and results, and revoke or remand them as appropriate. Having said that, let me give you my thoughts on the topic I was asked to address.

{4} There's a lot of confusion over fact and fiction about transgenic crops. As a scientist dedicated to following the data where ever they lead, I'd like to highlight some of these oft peddled fictions and then provide you with some facts. Among the oft peddled fictions are that foods derived through crops improved through biotech means were surreptitiously imposed on an unwilling public. A parallel fiction is that consumers want labels, but labeling has been stymied with the intention of keeping the public in the dark. Also that there are inadequate safety reviews and companies have been uncooperative in the pursuit of these reviews.

{5} Additional myths assert that biotech derived foods present novel food safety risks such as allergenicity, toxicity, etc; that there is inadequate knowledge of long term consumption impacts; and that environmental threats have been inadequately considered. Additional fictions are that these crops improved through biotechnology benefit only companies, not consumers or farmers, and that



they encourage monoculture and unsustainable agriculture or they encourage corporate control of food production and economic concentration. The opponents of biotech have it very easy. They have much more freedom to employ an artistic pallet, unhampered by facts. Some of this is pretty good, from an artistic point of view, but facts are stubborn and uncompromising. One of my intellectual heroes, Thomas Henry Huxley once said, "There is no sadder sight than to see a beautiful hypothesis rent limb from limb by packs of bloodthirsty facts."

{6} The first myth I'd like to debunk is that crops improved by biotechnology and the foods derived therefrom have been surreptitiously imposed on an unwilling public. Let me ask you a question, how much coverage has there been in newspapers or on the radio and in T.V. on these topics? Does anyone hazard to guess? I personally have been on every major news network, including Crossfire and Nightline, and I can't keep track of the clippings that my father, out in Arizona, sends to me in envelopes every week which he's been doing for about eighteen years. The problem here is not that we've been eating in the dark but we've been exposed to so much sunlight that we risk melanoma.

{7} Another myth relates to the regulations. The fact is that the regulations under which these products have been governed were promulgated under the Administrative Procedure Act ("APA"), via notice and comment rulemaking, which requires numerous opportunities for public comment, public hearings and so forth. There's been a whole heck of a lot of public notice. There have been public hearings at every significant juncture when any significant development's been announced by USDA, FDA, or EPA whether required by law under the APA or not. Routine permits continue to be promulgated under notice and comment rulemaking under the requirements of the FDA. Public databases on the USDA website provide the decision documents on each and every field trial, and there have been upwards of 10,000 field trials over the last fourteen or fifteen years, with crops grown on more than 30,000 test plots and commercial fields around the United States.

{8} Another myth is that consumers want labels. Benjamin Disraeli said, "There are lies, damn lies, and statistics." Push polls bought and paid for by the global protest industry suggests that consumers want labels. Polls that are based on that same context set by these push polls done by, for example, ABC news, continue to show the same sorts of things. However, if you were to do a poll that's actually designed to try to measure public opinion, rather than lead to a predetermined conclusion or generate sales or attention for your media outlets, you would get a different result. When FDA labeling policy is explained to consumers, we find that it is embraced by wide margins. Go to www.ific.org, the IFIC website – the International Food Information Council – and you will find that the existing labeling policy is embraced by 80% percent of the population – upwards of 80%, when the actual policy itself is explained to them.

{9} A choice to eat foods that have not been derived from crops and foods of biotechnology is in fact a reality for consumers in the United States today. It's difficult to achieve because as our first speaker, Ms. Hart, pointed out, the organic market is very small, but the organic folks have voluntarily separated themselves from the use of biotechnology; therefore, the folks who want to avoid biotechnology do have that option. You have to pay more, and it's hard to find sometimes, but it's there. Fact of the matter is that most consumers are not concerned on this issue. They don't want labels, and they wouldn't read them if they were there.

{10} Does anybody want to hazard to guess as to what the nature of the most often received phone call on the 1-800 telephone call lines set up by Kraft Foods was in the aftermath of the StarLink debacle? The most common phone call they got asked "When will taco shells be back on the market?" These food companies all maintain these 1-800 call lines and at no point have calls related to biotechnology

ever risen above one or two percent for more than a very brief period of time and those spikes are correlated with activist campaigns. Consumers are not concerned about this issue. Andrew Kimbrell for The Center for Food Safety has said, “We are going to force them to label this food. If we have it labeled, then we can organize people not to buy it.” Craig Winters has said “labeling has nearly the same effect as a ban.” The issue of labeling is a red herring. It’s not about consumer choice. It’s about activists who want to try to deprive consumers of choice.

{11} The issue of inadequate safety reviews is another red herring that’s often raised. The fact of the matter is that every reasonable question one could have imagined is asked of crops and foods improved through biotech, and some unreasonable questions as well. The fact is that far more rigorous scrutiny is applied to crops and foods improved through biotech than is applied to conventional or organic foods. Kiwi fruit makes a very good example. Does anyone remember a time when kiwi fruit was not available in the United States? I do. Let’s talk about food allergies. We know what causes food allergies. Depending on how you want to parse it, there are between six and twelve major categories of allergenic foods in the world. Chinese Goose Berry doesn’t rank even amongst the top twelve, but you will find it sometimes in the list of the top twenty.

{12} The issue of food allergies by the way is of particular importance to me personally, because I have a four and half year old son, a great kid and hell on wheels (he is my son...). He has a life threatening allergy to peanuts. I’m very interested in this issue. When you find out that your kid has an allergy like that, let me tell you, your marrow runs cold. Our families lives all changed forever when we learned that, and every day is laced with fear. This is a very big deal.

{13} Back to Kiwi fruit. Chinese Goose Berries are known to cause allergic reactions in some people. What kind of food safety clearance did we have to have before Kiwi fruit were allowed to be imported into the United States? One 8 ½ x 11 sheet of paper on which it was stated there is a history of safe use. Safe use including use which leads in some small portion of the population to sudden death by anaphylaxis. This is much less likely to happen with foods derived from crops and foods improved through biotechnology because of the prior screening for allergic potential they receive a level of scrutiny far in excess of what is applied to conventional or organic foods.

{14} As for assuring the safety of U.S. regulatory framework, our second speaker talked about this at some length. The fact of the matter is that a whole host of data are required on all reasonable questions from EPA, FDA, and USDA. Mr. Jaffe did point out a number of things that I think could be done to improve the system, but they are relatively minor. Inadequate knowledge of long term consumption impacts. Substantial equivalence which is key to the FDA’s regulatory policy, contrary to what many of the critics assert is not a presupposition of the process but is a conclusion that’s reached after asking and satisfactorily answering a whole host of questions about material composition and so forth.

{15} For long term consumption impacts, this again is a red herring. The crops improved through biotechnology that are intended for human consumption with very few exceptions contain exogenous proteins. We have done routine studies, and biotech companies do digestive fate studies with the proteins, and those studies routinely demonstrate that a protein subjected to digestive processes behaves like a protein which gets digested. In other words, it’s broken down into its constituent amino acids; this is also known as nutrition. There is not one shred of data anywhere in a huge body of experience to suggest that there would be any need for or justification of the sorts of long term consumption studies for whole foods that are sometime required for pharmaceutical compounds and so forth. There’s a whole host of differences, and we can go into these in much greater detail if you’d



like, but this is basically a smoke screen for confusing lay people.

{16} Environmental threats. Much is often made about pollen or gene flow. The fact of the matter is that pollen flows and genes move all the time. The question was raised about biotech corn. It's often raised in the last couple of years about the possibility of problems for biodiversity related to the integration of biotech corn traits into native land corn in Mexico. The fact of the matter is that half of the genome of a corn plant is composed of transposable elements of viral origin. They are not by any stretch of the imagination corn genes. Different strains of corn vary in their DNA content due to these elements by as much as 30%.

{17} Barbara McClintock got a Nobel Prize for looking at this. The key question is not will genes move or will pollen carry genes between one organism and another? This happens all the time. The key question is what are the impacts? This is not a difficult thing to figure out. The overwhelming preponderance of data and experience suggests that crops improved through biotechnology will have either no significant impacts or positive impacts on the other organisms and the environment with which they interact.

{18} I'd love to talk more about Monarch Butterflies. I have my backyard where I keep my organic garden filled with plants designed to attract Monarch Butterflies, but to quickly jump to the bottom line, as it turns out, the safest place for a Monarch butterfly larva to be is in a biotech cornfield and this was not something that was just discovered after the scientists did the research following John Losey's, science grade C+ experiment, but this is something that was anticipated by USDA. I happen to have been, prior to joining BIO, with USDA APHIS for eight years, and we explicitly considered the potential for impacts on non-target organisms including the Monarch Butterfly from the Bt corn that was the focus of so much entertaining newspaper coverage after Losey's paper was published. The available scientific data and information indicates a positive ecological effect when compared to the most likely alternative pest control measures, according to the EPA.

{19} Cui-bono, who benefits? The benefits are multiple and widespread. Most detailed data show that six crops currently in the United States produce an additional four billion pounds per year of food and fiber, increase farm income by \$1.5 billion dollars, and reduce pesticide volume by forty-six million pounds per year. Those are some significant benefits. The Australian Bureau for Agricultural Resource Economics concluded in a study published last week that crops grown via biotech would boost aggregate incomes for all regions by \$310 billion dollars by 2015, but the greatest impact would be on the poorest farmer's incomes and health.

{20} A bunch of folks have done some very good work. Partitioning these benefits, Greg Traxler at Auburn has shown about 60% of the benefit flows to the farmers, about 30% flows to the biotech companies that responsible for these innovations, with the remainder going directly to consumers. On the myth that biotech is responsible for encouraging monoculture and unsustainable agriculture, the fact is that biotech in soybeans has led to the adoption of low or no till agriculture enabling methods of production that are conserving of top soil and organic matter in the soil and therefore also of moisture. In an era of increasing drought and scarce fresh water, this is important.

{21} One critic, Dr. Jane Rissler, someone for whom I have a measure of respect, has argued that biotech is problematic because it involves substituting a gene treadmill for a synthetic chemical treadmill. This is true; it's what Rachel Carson told us to do. "A truly extraordinary variety of alternatives to the chemical control of insects is available. All have this in common: They are biological solutions, based on understanding of the living organisms they seek to control. . . . Some

of the most interesting of the recent work is concerned with ways of forging weapons from the insects' own life processes." Go back and re-read the last chapter in *Silent Spring*, "The Other Path." This is what we ought to be doing.

{22} Again on the monoculture culture issue, increasing reliance on one or two different crop varieties. Let's look at the data on introduction to new soybean varieties by the largest soybean company in the world Pioneer Hi-Bred. From 1991 to 1995, the average number of new soybean varieties introduced per year was twelve; from 1996 to 2001 the average number of soybean varieties was twenty-one. What happened in 1996? Biotech varieties got introduced. In point of actual fact, biotechnology has dramatically increased the biodiversity in the agricultural systems that we work on, both in terms of the varieties that are cultivated and because of the smaller environmental footprint and the improved ecological health of the biological ecosystem itself.

{23} Biotech enhances corporate control of food production and economic concentration. Well, one of the most powerful forces of human history is consumer choice. Consumers choose cheaper food. This has driven concentration in the agriculture industry since long before Watson and Crick, whose fiftieth anniversary we are only this year celebrating. What does human nutrition look like in the areas of the world where there is the lowest corporate control of food production? I will leave that as an exercise for the audience. The fact of the matter is that the crops and foods improved through biotechnology have been subjected to more scrutiny in advance, in depth, and detail, than any others in human history. It's not about safety. Ag-biotech has become a lightning rod, a stalking horse and a surrogate for other issues: concentration, globalization, concerns over cultural problems and so forth.

{24} There is a positive alternative however, and that is increasing public sector funding for agricultural research and development. This is something we need to be doing. Every time I go up on the Hill, I lobby on this issue with legislators. I invited the environmentalist groups who are opposed to biotechnology to join me in doing that, and the most I've ever gotten is a suggestion that, "Well, we might argue for increasing support for organic agriculture . . ." Okay, that's fine, it has its place, including in my backyard, but our needs are so great that we need every arrow in the quiver and every tool in the tool box. One of the founders of GreenPeace, Patrick Moore, has said "The campaign of fear now being waged against genetic modification is based largely on fantasy and a complete lack of respect for science and logic." James Watson has said, "When it comes to considering the risks of recombinant DNA, we shy at kittens, and cuddle tigers." Thank you for your attention.

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