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REMARKS ON REGULATING GENETICALLY MODIFIED FOODS IN THE UNITED STATES

Remarks by: Gergory Jaffe*

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{1} Thank you very much for inviting me here today. I'm going to use PowerPoint here, but I will try to keep my comments brief. I'm going to spend just a minute or two introducing my organization to you and our biotech project. Then I'm going to talk a little about the regulatory system and what I see are some of the inadequacies in the current regulatory environment for agricultural biotechnology.

{2} I work for the Center for Science in the Public Interest, which is a non-profit consumer advocacy organization located in Washington, D.C.; we've been around for about thirty years. We publish a Nutrition Action Health newsletter. I left a copy of our issue on genetically engineered foods out on the table out there. We have 800,000 subscribers in the U.S. and Canada. We take no industry funding or government funding. Eighty to ninety percent (80-90%) of our budget comes from our member subscribers through their subscription rates and donations. About the last ten percent (10%) of our budget comes from independent foundations.

{3} Our biotech project was established a little over two years ago. The purpose was to identify the benefits and risks of this technology, to establish a strong regulatory system for it in the U.S. and abroad and to educate and inform the public about biotechnology. CSPI prides itself on advocating policy based on the science and where the science takes us. We felt there was a need for a moderate position on agricultural biotechnology and that's how we got involved in the issue. The positions we've taken so far are that we think that current crops in the U.S. appear to be safe to eat and that the environmental risks are manageable. So we support those products, including the RoundUp Ready soybeans and the Bt corn and cotton that is out there.

{4} We've told our 800,000 subscribers that they should feel comfortable eating that food and that it is safe. We see some benefits from these crops – some environmental benefits and some benefits to farmers, and to the extent those exist we want to support those. We feel that you should address new products on a case by case basis. A technology in and of itself isn't good or bad. You have to take the applications of that technology and take a look at those applications and ask are those safe? Do those have risks attached to it? I think the debate about agricultural biotechnology in general just gets a lot of people talking about the technology generally and you can't do that – you have to look at individual applications. But we do think the regulatory system needs strengthening. I spend a lot of my time as a lawyer working to strengthen that system.

{5} What are my goals for the regulatory system? I put them into one overarching goal, which is to ensure that these products are safe for humans and the environment. You want to make sure the products get a thorough evaluation to determine their safety before they're eaten, and you want to make sure they get an environmental assessment to determine whether they have any potential environmental effects and if they do, whether those risks can be adequately minimized or eliminated



through conditions of approval.

{6} So what are the attributes of a strong regulatory system? Well there are a couple of them that I focus on. One is having adequate legal authority. Do the regulators have the authority to mandate review, to mandate conditions upon which crops should be grown or approved? Are there consequences to not coming into the regulatory system or not abiding by those conditions? Do the agencies make a determination? Can they actually tell the public that it's safe? Do they have the authority to do that?

{7} Another attribute is an open and transparent system. Can the public get data? Can the public see what's going on? Does the public know about the process? Participation is very important in the U.S. system. Does the public have an opportunity to give its opinion? Do they participate in this process, not to make the decisions of the governments and the experts but to give its opinion. Finally, does the system have appropriate authority or the appropriate ability to oversee the industry compliance with the regulations or take enforcement when needed? Can they do inspections, compliance, and enforcement?

{8} So I try to look at these attributes and say "Well, how does the U.S. system rank against those?" I think there are some problems that need to be fixed, and I want to spend some time going through those problems. I'm going to give just a couple of quick examples here, because I really don't have much time and I want to give time for the panel, but the first one, is the system mandatory? Well there are parts of it that are voluntary. FDA's review of genetically engineered crops to ensure they're safe to eat is a voluntary process. I understand that all the companies have participated in that voluntary process and they've all provided data, but it's a voluntary process.

{9} The only thing the FDA approves right now is food additives. Biotech crops are not considered food additives; they are considered "Generally Recognized As Safe," so the FDA makes no determination on whether a crop is safe for human or animal consumption. They don't tell the public it's safe, and they don't have any authority to mandate pre-market approval. In most other countries, such as in Europe, Canada or Japan, mandatory pre-market review is required. I think that is a big problem in the regulatory system – a big gap is not having a mandatory food safety review for crops.

{10} We did a report, it's on our website, that came out in January, where we looked at the voluntary consultation process. We looked at the data that was provided and the FDA analysis of it. I'm not going to go into the details on it but there are a lot of problems with that process. FDA didn't get the data that it desired in a number of cases. It missed obvious errors in data that was presented to it by the companies. Certain important toxicants and nutrients weren't tested and the data didn't contain sufficient detail to really make an assessment.

{11} Another process that I think has some need for improvement is the FDA's approval process for transgenic animals. They treat transgenic animals as animal drugs under Section 512 of the Federal Food, Drug, and Cosmetic Act. Section 512 has mandatory pre-market approval process and I applaud that – I think that's good and that process is very good at reviewing for human and animal safety. FDA is not going to let anything through that process unless they're sure that if humans can eat it – if that drug gets into the food that it's going to be safe for them to eat and that, that drug is also safe for the animals. So I think those are good, and that's a positive part, but there are some negatives to this process that I think need to be changed.

{12} One is that the Section 512 process is not transparent. By law, Congress established that the application itself, the fact that the companies are talking with FDA is confidential and FDA cannot tell anybody that there's an application before the application is approved. Even when it is approved there won't be access to the data, including the underlying safety data. The process is not participatory,

there's no public input in that process, as it is a behind close door process. I think that's problematic. I think there won't be public trust in those decisions especially when you consider that people are going to eat whole genetically engineered salmon. I think that's going to be a real problem.

{13} Another area where I think there are some gaps in legal authority and gaps in environmental review is where the regulatory system looks at adequate measures to ensure environmental safety. As it is currently, the FDA under the transgenic animal process lacks authority to address environmental concerns associated with transgenic animals. They may do some assessment under the National Environmental Policy Act, but they have no authority to act on those problems to deny an application if there is an environmental problem or to impose environmental conditions on that approval. Similarly, the USDA, who does look at environmental issues for transgenic crops in some cases, doesn't do any assessments prior to releasing those crops. Ninety or ninety-five percent of the crops that are released for field trials don't have any assessment done with them. When I'm talking about environmental assessment here, I'm not talking about environmental assessment (EA) as required under NEPA, the National Environmental Policy Act, but I'm just talking about an individual case-by-case assessment on whether that crop has an environmental problem or might cause environmental problems. The National Academy of Science just recently came out with a report last year that the environmental assessments conducted by the USDA are inadequate, and I agree with that. They don't look into all the environmental issues that they should.

{14} Finally, one of the things that I think is a real problem with the USDA system is that they don't have the authority over these commercial products that have obtained non-regulated status. Each of the biotech crops that is out there, like RoundUp Ready soybeans or the Bt corns, at the end of the process, USDA comes out and say they are not plant pests anymore and deregulates them. I don't disagree with that decision that they're not plant pests, but what that means is that they're out of the regulatory system. If a problem comes up, like an environmental problem, the government has no ability of jurisdiction to address it. There's no environmental monitoring to see if there are problems, and there's no real ability to come in and address any environmental problem.

{15} A final issue I want to discuss in terms of regulatory system is oversight and adherence to permit permits. We've heard from previous speakers about StarLink, and there were violations by Pioneer and Dow for trials in Hawaii this past year. The University of Illinois had some transgenic pig violations a couple of months ago. The real question is, do the agencies have the will and resources to oversee the industry and punish the bad actors?

{16} What are some of the solutions to some of these problems? I'm going to give solutions in three different areas. First for legislative changes, Senator Durbin from Illinois last Congress introduced the Genetically Engineered Food Act that does set up a transparent and mandatory approval process for biotech crops. So, it addresses the voluntary aspect I talked about earlier. It provides explicit environmental authority for transgenic animals to FDA addressing that issue that I addressed earlier. It also opens up the review process for transgenic animals giving the public access to data and an opportunity to participate. Finally, it also requires a pre-market food safety approval for any engineered food crop including the "pharming" crops. So if you engineer a food crop, it's go to through a mandatory approval process. So that's one way to address a lot of these issues and I think it's the only way to address some of them. There is no other way but legislative.

{17} There are administrative changes that also could be done to improve the regulatory system. Instead of deregulating GE crops at the USDA, USDA could keep them in the system so that you can address environmental concerns. USDA could also require environmental assessments before the permits are issued. Then there's the oversight changes and there are things that could improve



it. We need to make sure that there's adherence to permits out there because the government could write whatever conditions they want into a permit or registration, and if they're not abided by, they're meaningless – they're not worth the paper they're written on. Clearly this industry has shown that they need to have that oversight because they have violated on a number of occasions. So I would like to see a strong inspection system, third-party independent auditing of compliance with permits, documentation requirements, certification requirements, and strong penalties as a deterrence.

{18} I don't want to take any more time, but "pharming" crops are a big issue out there, they're not covered under the food laws because there's an "intent" part to those statutes, and these crops are not intended to be used for food, yet they might get into our food. The Federal policies that have come out in the past year really don't adequately address this issue. OSTP had a proposal in August but it specifically exempted "pharming" crops from it, and FDA and USDA came up with a guidance in September but I stopped counting how many "may's" or "you should's" or "you could do this" it had in it – it didn't require anything. It left it up to the industry to decide really what they wanted to do.

{19} USDA came out with some permit conditions just this past week and they're definitely a good start, but I come back to it's not just the permit conditions, it's whether they're actually put into place, and that's a big question mark. So what would happen for these "pharming" crops? Again, strict containment, a mandatory pre-market food safety approval if they're being used for food crops, and much more oversight by both the Federal Government and third-party groups are needed. Thank you.

* Gregory Jaffe earned a B.A. degree in Biology with high honors from Wesleyan University and received his J.D. from Harvard Law School. Mr. Jaffe first worked as a Trial Attorney for the United States Department of Justice's Environmental and Natural Resources Division for seven years. He worked as Senior Counsel with the U.S. Environmental Protection Agency (EPA) in the EPA's Air Enforcement Division. Since leaving the EPA, Mr. Jaffe serves as the Director of the Project on Biotechnology at the Center for Science in the Public Interest (CSPI). CSPI is a non profit consumer advocacy organization involved in food and nutrition issues and was instrumental in getting Congress to require nutrition facts labels on food in the United States. Throughout his career, Mr. Jaffe has published numerous articles on agricultural biotechnology, and Mr. Jaffe has spoken at over a dozen conferences addressing agricultural biotechnology issues in both the United States and abroad. Mr. Jaffe is currently recognized as an expert on the U.S. regulatory structure for agricultural biotechnology, as well as consumer issues pertaining to agricultural biotechnology.