

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

Participants: L. Val Giddings, Gregory Jaffe & David Hegwood
Moderated by Kathleen Hart

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Ms. Kathleen Hart: {1} Thank you all. In my opinion, containment of pharmaceutical GM crops is essential and hard to do. The USDA just recently came up with some new guidelines for genetically modified pharm plants, but how can the public have an input into what's going on if they don't even know where the crops are growing, or what's in the crops, because this is protected as confidential business information? Should the public have a say? How would we accomplish--giving the public a say about whether they want genetically engineered wheat, even aside from the export issues. Third, I understand GE salmon is very close to being approved and released. That's a containment issue of another kind. The fourth issue is that there are all kinds of organisms that don't even fall under EPA, USDA, or FDA jurisdiction, such as GE mosquitoes, and so forth. So, is there some way that you would want to propose changes to the regulations that would help bring the public into the debate? A couple minutes each.

Mr. Gregory Jaffe: {2} Well I'm not going to tackle all those, it's too much, but my view on transparency and public participation is that regulatory processes should be open. I do also believe that there is genuine confidential business information. To the extent that some information is genuine confidential business information and qualifies under the case law that exists out there, it should be protected. In some cases that may be the test plot where something is grown. That doesn't mean you couldn't find out the state it's grown in or the county it's grown in; that might not be confidential.

{3} Similarly, in some cases the drug or the specific product may be confidential. A lot of these things are patented; a lot of those things are out there. One of the things about something being confidential business information is that it's the traits you get from the company that are protected. My criticism of the system is that I think the government has taken at face value a lot of the companies' claims of CBI. The way the system is supposed to work, the government is supposed to question those and only protect what is truly confidential.

{4} My answer to your question is, if information is truly confidential then, yes, the company should have a right to keep it confidential, but the agency should be looking closely at that and they should be doing it based on the case law that exists out there. As to your other remarks, such as about the wheat,





I agree with David Hegwood. Our regulatory system and agencies like FDA should deal with risks; they should deal with the food safety risks. That's what we want them to do, be an independent agency that looks at the risks.

{5} Other social issues, marketing issues, other kinds of things, I agree that those are big concerns and they should be addressed but they shouldn't be addressed by regulatory agencies that are addressing safety concerns. I don't think you should mix jurisdictions. I think one of the things that our society has to figure out through Congress and the Administration is, what are the forums to address those other social, ethical, or other factors? I'm one who's not advocating FDA to step in to do that.

Mr. David Hegwood: {6} Well, I will briefly address the issue of pharmaceutical field trials. I think the first point to emphasize is these are field trials. This is research and development. These are not commercialized products. These are not products that humans are going to consume. This is strictly research and development at this stage. So if the public is saying, "We want to know where these are grown and what they are," I guess I would have to ask "Why do you want to know?" Is it because you're afraid you're going to be consuming them? If you are, I can tell the answer is no, you're not. The objective of our regulatory system is to ensure that you don't consume the goods. That's the whole purpose. So, at some point should there be public input into the process before these things are commercialized, if and when they are ever commercialized? Absolutely, and it will happen. The process is in place, that's what the regulations say. Again, as Greg Jaffe said, you have to respect the confidential information. This is not a new issue; this is something we've been dealing with for as long as we've had business.

Dr. Val Giddings: {7} Yes, I'd like to take all of the questions, but I'm not sure I can remember them all. First, I'll point out that it is not true that we don't know where these things are being grown. Confidential business information sometimes protects the specific cooperator and the individual farmer who is growing these crops, but even when that claim is made, the county in which this is grown is specified several places in the environmental assessment by the companies in each and every request for permission to grow this stuff. This is on record; you don't have to believe me. Go to the USDA website, and you can download these tables. You can spend the rest of your natural life, or a good portion of it, downloading and reviewing this information.

{8} On to the salmon issue and containment. Dr. Hoover has said there have not been any surprises to date on the transgenic crops produced for food use and so forth – and that's true. He did see, however, assert a surprise with the salmon. The one surprise that has come up with this transgenic salmon, after extensive analysis, has been that it contains a slightly higher yet significant concentration of the omega three fatty acids that has everyone encouraged to eat salmon. The only surprises that I know of so far have been positive surprises.

{9} On the issue of containment, the transgenic salmon that are being developed are number one, all female, and number two, sterile. Okay, so these salmon, even

if they are put in commerce, and even if they are released in ocean pens which is conventional today, these salmon represent a substantial and significant improvement in the level of safety over and above what we already see with the existing salmon farming technologies.

{10} So that highlights on a very important question to focus on when we're talking about safety of crops and foods. The right question to ask isn't how safe is it or what is the level of safety in terms what probabilities or consequence A, B, or C. The question that is really most useful to ask is how does the level of safety for this new product compare to the level of safety that we already accept as routine with the existing products? Without exception, in each and every case to date, the answer to that question for crops and foods produced by a biotech method are at least as safe and in numerous cases they are safer than those that we already now enjoy.

Ms. Kathleen Hart: {11} Thank you all for your participation.

