Consumers Union Makes False Claims Against the Safety of Genetically Modified Foods Based on Ideology not Science.

The ideologically driven, anti-technology campaign to restrict access to safe, sustainable and affordable foods improved through biotechnology got a boost when Vermont Governor Pete Shumlin signed into law a new measure that mandates the labeling of foods modified through genetic engineering sold in Vermont.

This campaign in support of the law is based on financial self interest and fear, not on reasoned policy designed to inform and protect consumers. Since other states are considering similar laws based on the same faulty reasoning, a detailed consideration of the argument is timely. To test the misleading statements and mischaracterizations of the labling campaigners I present testimony below from Michael Hansen, Ph.D., Senior Scientist with the Consumers Union. This testimony was presented as part of the New York State Assembly Standing Committee on Consumer Affairs and Protection's Public Hearing on the Use of Biotechnology in Foods and the Effects on Consumers at Lehman College, on Tuesday, July 30, 2013. I include Hansen's statements on GMOs and provide a factual analysis with documentation correcting his false and innacurate claims.

The italicized portions below are statements by Assembly Members, or by Michael Hansen. Some of Hansen's many false and misleading statements are highlighted. Corrections follow, in regular font, bold and slightly larger.

I will call the first witness and that is Michael Hansen, Ph.D., Senior Scientist from Consumers Union. Okay would you raise your hand please? Do you swear that on the testimony you give will be truth?

MICHAEL HANSEN, PH.D., SENIOR SCIENTIST FROM CONSUMERS UNION: Yes I do.

ASSEMBLY MEMBER DINOWITZ: Okay please state your name and then proceed.

HANSEN: Yes, my name is Michael Hansen. I'm a senior scientist at Consumers Union. That's the policy and advocacy arm of consumer reports and we're headquarters in Yonkers New York and I want to thank you. I'm here to testify in support of the A3525A. A bill that require labeling of foods that have been derived from genetically engineered ingredients.

As I will discuss in my testimony, …unlike other developed countries, the US does not require genetically engineered foods to be proven safe before they can go on the market despite significant safety concerns. But even if all reasonable safety testing were required, certain individuals could still have unusual allergic or other adverse responses that would not be detected beforehand. There could also be unexpected effects, just as there sometimes are with pharmaceutical products, despite extensive premarket testing. For all these reasons, it's important to label genetically engineered foods so negative effects can be noticed and identified and so consumers who simply want to avoid these new foods can do so if they wish.

These claims are either factually incorrect or misleading. FDA requires *all* foods placed on the market in the United States to be safe. This requirement applies equally to "bioengineered" foods and all others. Placing any unsafe food on the market is a violation of the Federal Food Drug & Cosmetic Act carrying criminal penalties. To ensure that bioengineered foods meet this safety requirement, FDA has based its review process and regulations on the findings of international working groups of experts. These have concluded after many years of detailed consideration that

- **bioengineered foods are not intrinsically different from other foods;**
- **the process of producing them and the attendant potential hazards are no different than those we are familiar with from other foods; and that**
- **absent any change in material composition resulting from the "bioengineering", such foods are "substantially equivalent" to other foods.**

For these reasons, FDA concluded that specific regulations and labeling requirements for bioengineered foods are scientifically unjustifiable. There is a strong, worldwide consensus of scientific opinion in agreement.

The claim of "significant safety concerns" is false, robustly contradicted by the scientific literature, worldwide scientific opinion, and vast experience.

Some representative voices include the following:

> **"Indeed, the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods; and if there are unforeseen environmental effects - none have appeared as yet - these should be rapidly detected by our monitoring requirements. On the other hand, the benefits of these plants and products for human health and the environment become increasingly clear."**
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> > **--European Commission, Press Release of 8 October 2001, announcing the release of 15 year study incl 81 projects/70M euros, 400 teams (http://ec.europa.eu/research/fp5/eag-gmo.html and http://ec.europa.eu/research/fp5/pdf/eag-gmo.pdf)**
>
> **"The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies…"**

http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf

"…because the technique is so sophisticated, in many ways it is probably safer for you to eat GM products - plants that have been generated through GM - than normal plant foods, if you have any sort of reaction to food, because you can snip out the proteins that cause the negative reaction to certain parts of the population."

--Sir David King, Chief Science Advisor, UK. The Guardian Unlimited, 27 November 2007
http://www.guardian.co.uk/gmdebate/Story/0,,2217712,00.html

"In contrast to adverse health effects that have been associated with some traditional food production methods, similar serious health effects have not been identified as a result of genetic engineering techniques used in food production. This may be because developers of bioengineered organisms perform extensive compositional analyses to determine that each phenotype is desirable and to ensure that unintended changes have not occurred in key components of food." (p. x).

--National Academy of Sciences, 2004. Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. National Research Council, Washington DC. 256pp. ISBN 0-309-53194-2.
http://www.nap.edu/catalog/10977.html.

"…in consuming food derived from GM plants approved in the EU and in the USA, the risk is in no way higher than in the consumption of food from conventionally grown plants. On the contrary, in some cases food from GM plants appears to be superior in respect to health."

--- Union of the German Academies of Science and Humanities. Commission Green Biotechnology, InterAcademy Panel Initiative on Genetically Modified Organisms. Group of the International Workshop Berlin 2006. "Are there health hazards for the consumer from eating genetically modified food?" at
http://www.akademienunion.de/_files/memorandum_gentechnik/GMGeneFood.pdf

"If we look at evidence from [more than] 15 years of growing and consuming GMO foods globally, then there is no substantiated case of any adverse impact on human health, animal health or environmental health, so that's pretty robust evidence, and I

would be confident in saying that there is no more risk in eating GMO food than eating conventionally farmed food."

Anne Glover, Chief Scientific Adviser, European Commission, 2012
http://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=9966

"GMO products have been tested to a particularly high extent and are subjected to rigid legislation control."

--Commission on Green Biotechnology, Union of the German Academies of Science & Humanities, at www.abic2004.org/download/reportongmohazards.pdf

"Food from GM Maize is more healthy than from conventionally grown maize… samples with the highest fumonisin concentrations are found in products labeled 'organic.' "

--Commission on Green Biotechnology, Union of the German Academies of Science & Humanities, at www.abic2004.org/download/reportongmohazards.pdf

"…the dangers of unintentional DNA mutation are much higher in the process of conventional plant breeding… than in the generation of GM plants. Furthermore, GM products are subject to rigid testing with livestock and rats before approval."

--Commission on Green Biotechnology, Union of the German Academies of Science & Humanities, at www.abic2004.org/download/reportongmohazards.pdf

"Whereas for conventional varieties there is no legal requirement for allergy tests of their products, for GMO products, very strict allergy tests are mandatory… For this reason, the risk of GM plants causing allergies can be regarded as substantially lower than that of products from conventional breeding."

--Commission on Green Biotechnology, Union of the German Academies of Science & Humanities, at www.abic2004.org/download/reportongmohazards.pdf

As for Hansen's claim of "unexpected effects" – to date there are none reported, and

"According to present scientific knowledge, it is most unlikely that the consumption of …transgenic DNA from approved GMO food harbours any recognizable health risk."

--Commission on Green Biotechnology, Union of the German Academies of Science & Humanities, at www.abic2004.org/download/reportongmohazards.pdf

Unlike conventional or organic foods, bioengineered foods are routinely screened in the US and other industrial nations (per regulations rooted in the OECD guidelines) to ensure they contain no toxins or known allergens. The emergence of previously unknown, novel allergens is so vanishingly rare as not to constitute even a remotely legitimate concern[1]. No such hazards have ever been reported from bioengineered foods in the scientific literature, nor any credible hypothesis through which such hazards might possibly arise.

With respect to allergenicity, it is clear that genetically improved foods (GIFs) are the safest foods available. Opponents have repeatedly claimed the potential for hazards where they simply do not exist, going so far as to insinuate that the reported increase in food allergies is linked to the introduction of GIFs into the food supply beginning in the mid 1990s. Indeed, one has gone so far as to claim bioengineered foods are responsible for increased reports of celiac disease, a claim absurd on its face, as there is no biotech improved wheat on the market. It was quickly repudiated by the Celiac Disease Foundation, but it remains on opposition websites and is regularly invoked.

The fact is, we know what it is about food that poses hazards for consumers. The overwhelming majority of negative health outcomes from food consumption is caused by foodborne pathogens. The Centers for Disease Control issues weekly and annual reports from which any mention of genetically improved foods is conspicuous by its absence.

The claim, therefore, that labeling is needed to inform consumers of potential hazards is not only unfounded, but the opposite of the truth: the only safety differential ever reported between bioengineered and other foods shows the bioengineered foods to be safer.

The claim that labels are needed to enable consumers who may wish to avoid bioengineered foods is also false – consumers already have numerous options to avoid bioengineered foods: they are free to choose to buy food carrying the USDA Organic label, or foods certified "GMO Free" under a number of voluntary certification schemes. There are even smartphone apps that enable consumers to scan a barcode to get an instant read on whether or not a food contains "GM" ingredients. There is, in fact, a dedicated PLU/SKU to identify foods containing

[1] Substances featured in reports of "new" allergens fall overwhelmingly into the well-established categories of foods known to be allergenic, e.g. http://www.sciencedirect.com/science/article/pii/S0091674995700358 and http://www.karger.com/Article/FullText/113512.

biotech derived ingredients, and hundreds of thousands of products around the world that are so encoded.

there's global agreement that genetic engineering is different than conventional breeding and that there should be required safety assessments before these products come on the market.

This assertion is false. Plant breeders and credible scientists around the world generally agree that the techniques used to produce transgenic plants, derived directly from natural phenomena, are but an extension of traditional plant breeding, and that the potential hazards are the same (see http://www.amazon.com/Plants-Genes-Biotechnology-Maarten-Chrispeels/dp/0763715867 and http://www.amazon.com/Mendel-Kitchen-Scientists-Genetically-Modified/dp/030909738X).

The U.S. National Academy of Sciences explicitly rejected this claim in its very first publication in this area "Introduction of Recombinant DNA-Engineered Organisms into the Environment – Key Issues (National Academy Press, Washington, D.C., 1987) and has upheld this view in every subsequent study. The Government of Canada in its regulatory structure has specifically repudiated the assertion that plants improved through recombinant techniques are necessarily and intrinsically different than those produced through conventional breeding (seehttp://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/novelty/eng/1338181110010/1338181243773). The government of Australia has done likewise (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-index-1#act) and the vast preponderance of scientists around the world concur in this assessment.

The human safety problems that could arise from GE are the introduction of new allergens or increased levels of naturally occurring allergens, changed levels of plant toxins and changes in nutrition. There can also be unintended effects.

There's been global agreement through Codex Alimentarius that's the food standard setting organization of the UN.

They've done a number of topics on this. The US is alone among all the developed countries. We do not admit that generic engineering is different than conventional breeding.

Our policy which was put out in 1992, was promulgated by then Vice President Dan Quayle who was a deregulatory initiative.

So the FDA says genetic engineering is an extension of conventional breeding. There's no required safety assessment. There's only the safety consultations where the companies make their own decisions. I would point out that in 2001 the FDA also put out a policy statement, that admitted that genetic

engineering is different than conventional breeding and does raise safety issues. Yet the FDA is still regulating GEN to the 92 policy.

In June of [2012], the American Medical Associations House of Delegates, they changed their position to one where now they support mandatory premarket safety assessment. As they said quote "Our AMA supports mandatory premarket systematic safety assessment of engineered foods."

The claim above is false. It is designed to mislead people to believe the AMA supports Hansen's opinions on safety and labeling of bioengineered foods. It does not. The AMA does support mandatory safety assessments (as have the biotech companies themselves, for many years). The AMA's 2012 statement changes nothing, but in fact reaffirms its previous views (adopted in 2000) on the safety of foods derived through biotechnology, and their opposition to special labeling for them. It states

> **"*…the FDA's science-based labeling policies do not support special labeling* without evidence of material differences between bioengineered foods and their traditional counterparts. *The Council supports this science-based approach,* and believes that thorough pre-market safety assessment and the FDA's requirement that any material difference between bioengineered foods and their traditional counterparts be disclosed in labeling, are effective in ensuring the safety of bioengineered food. To better characterize the potential harms of bioengineered foods, the Council believes that pre-market safety assessment should shift from a voluntary notification process to a mandatory requirement. *The Council notes that consumers wishing to choose foods without bioengineered ingredients may do so by purchasing those that are labeled "USDA Organic."***

The full text of the AMA's latest statement can be found here: http://www.ama-assn.org//resources/doc/csaph/a12-csaph2-bioengineeredfoods.pdf.

These most recent statements from the AMA are fully consistent with their earlier positions (2000), in which they concluded "The AMA believes that as of December 2000, there is no scientific justification for special labeling of genetically modified foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education. " And further "Federal regulatory oversight of agricultural biotechnology should continue to be science-based and guided by the characteristics of the plant, its intended use, and the environment into which it is to be introduced, not by the method used to produce it, in order to facilitate comprehensive, efficient regulatory review of new genetically modified crops and foods."

Hansen: I'd like to say there's also evidence of health problems. The FDA is poised to approve that genetically engineered salmon has been engineered to reach market weight in half the time of wild salmon. However the company's own data suggest there could be allergy problems.

This allegation is false.

There are significant differences between the regulatory oversight administered by FDA for plant derived foods and feeds, and that for foods from bioengineered animals. Risk assessments and pre-market approvals for foods derived from bioengineered animals are mandatory, and conducted under the authority of the New Animal Drug regulations, in a manner comparable to or more rigorous than those required for food additives (see 21 CFR 514.1.b.g).

A full record of the documents provided by the FDA for the Veterinary Medical Advisory Committee meeting and Public Hearing held from 19-21 September, 2010, can be found here. FDA specifically addressed the allergenicity question in a Q&A section entitled "Key facts commonly misunderstood," found here , stating "*Will people be allergic to the AquAdvantage Salmon specifically because it has been genetically engineered?* [Answer] No. People who are allergic to Atlantic salmon will likely be allergic to AquAdvantage Salmon because it is a finfish (one of the eight most allergenic foods in the U.S.), not because it has been genetically engineered." The complete briefing packet provided by FDA, incorporating data from the company, is found here. The allergenicity issue is discussed on pp. 106-15. It states ", the question was asked whether the edible tissue from GE salmon is more allergenic than the non-GE comparator" and concludes "Triploid ABT salmon pose no additional allergenic risk than control Atlantic salmon. Insufficient data and information were available from which to draw a conclusion regarding possible additional allergenic risk posed by diploid ABT salmon."

It must be noted that the "possible additional allergenic risk posed by diploid ABT salmon" would be irrelevant to consumers, as the fish intended for consumption is the triploid. Further, the context remains that "People who are allergic to Atlantic salmon will likely be allergic to AquAdvantage Salmon because it is a finfish (one of the eight most allergenic foods in the U.S.), not because it has been genetically engineered…" In other words, there are no novel risks here, nor any unfamiliar risks, but only the very same risks with which consumers are already confronted because the salmon "is a finfish" and not because it has been bioengineered.

Hansen further suggests that changes in expression patterns of genes encoding for the synthesis of allergens could increase salmon allergenicity. But the range of expression levels of allergenic proteins varies widely within varieties of non GM food allergens, and they have

never been observed to result in changes in allergenicity (see here). Hansen's assertion of "evidence of health problems" is not supported by any data or experience.

A problem with the safety assessments that are done on engineered plants, is there's very few long term feeding studies. They're usually 90 days or shorter.

The reason food safety studies are usually 90 days or shorter in duration is that animal feeding studies lasting longer virtually never add useful understanding. This is recognized in the guidelines on best practices for animal feeding studies established by expert working groups, which set the 90 feeding study as the standard. Toxicologists and food safety professionals are unanimous in their view that long term safety studies are virtually useless in determining food safety. As the GAO has concluded,

> **Monitoring the long-term health risks of GM foods is generally neither necessary nor feasible, according to scientists and regulatory officials we contacted. In their view, such monitoring is unnecessary because there is no scientific evidence, or even a hypothesis, suggesting that long-term harm (such as increased cancer rates) results from these foods. Furthermore, there is consensus among these scientists and regulatory officials that technical challenges make long-term monitoring infeasible.**
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> **US General Accounting Office, GAO-02-566, 2002 at http://www.gao.gov/new.items/d02566.pdf**

Nevertheless, and again, contrary to Hansen's claim, a number of well designed, long term studies have been done. All of them contradict Mr. Hansen's claims.

There was a carefully designed over a meta-analysis of published feeding studies, that looked at animals eating GE corn or soy and they found damage in the kidney, liver and bone marrow, which could be potential indicators of onset of chronic diseases.

Hansen does not provide a specific citation here, but in other presentations he has used identical language to invoke the Seralini study, discussed below.

Last October there was a long term two year feeding study. That found that GE corn caused tumors and premature death. The study by Doctor Erik Giles Séralini and colleagues was viciously attacked in the media by Pro GE and Industry Affiliated scientist, in what appears to have been an orchestrated campaign. What wasn't said is that the French Food Safety Agency and the European Food Safety Authority have functionally agreed with Doctor Séralini that such long-term safety assessments must be done. In fact, on June 28th, the European commission announced that they were spending three million Euros, to fund a two year cancer study on the same GE corn variety NK603 that DR. Séralini and his colleagues used.

These claims are contradicted by the historical record. The "attacks in the media" aimed at the Seralini "study" were the direct consequence of its unusually poor design, execution, and analysis (see http://parrottlab.uga.edu/parrottlab/Publications/Arjo-et-al-TRAG-2013.pdf and http://www.vegangmo.com/?p=711) and the unprecedented media manipulations imposed on journalist prior to its release, in an attempt to compel favorable media coverage. The criticisms of the study and the way it was released were spontaneous and widespread among credible scientists and journalists . That is how peer review works. The criticisms were, in fact, more severe than is commonly seen, but this was entirely due to the extraordinary shortcomings in design, execution, and interpretation of the experiment, and the unprecedented departure from the norms of publication designed to produce slanted media coverage.

The claim that *"the French Food Safety Agency and the European Food Safety Authority have functionally agreed with Doctor Séralini"* is contradicted by the historical record. Regulatory bodies in Europe and around the world uniformly rejected the study, and have made the following statements:

> **European Food Safety Authority: "EFSA is presently unable to regard the authors' conclusions as scientifically sound."**
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> **Six French National Academies of Science (Agriculture, Medicine, Pharmacology, Sciences, Technology, and Veterinary Medicine) condemned the study, stating "Given the numerous gaps in methods and interpretation, the data presented in this article cannot challenge previous studies which have concluded that NK603 corn is harmless from the health point of view, as are, more generally, genetically modified plants that have been authorised for consumption by animals and humans." They further dismissed the study as "a scientific non event" that served only "to spread fear among the public that is not based on any firm conclusion." These findings were echoed by the French Higher Biotechnologies Council (HCB) and the National Agency for Food Safety (ANSES).**
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> **Federal Institute for Risk Assessment: (BfR, Germany): "The authors' main statements are not sufficiently corroborated by experimental evidence, due to deficiencies in the study design and in the presentation and interpretation of the study results."**
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> **The Australia New Zealand Food Safety Authority stated "On the basis of the many scientific deficiencies identified in the study, FSANZ does not accept the conclusions made by the authors and has therefore found no justification to reconsider the safety of NK603 corn, originally approved in 2002." Canada concluded "The overwhelming**

body of scientific evidence continues to support the safety of NK603, genetically modified food and feed products in general, and glyphosate containing herbicides."

Indeed, the condemnation of the Seralini study from the international scientific and regulatory community was so deep, broad, and spontaneous, that even Marion Nestle, NYU Professor of Nutrition and food safety advocate long known for her skepticism of agricultural biotechnology, agreed: "It's a really bad study." One blogger distilled the consensus, and coined the "Seralini Rule": "If you favorably cite the 2012 Séralini rats fed on Roundup ready maize study, you just lost the argument."

In the end, the evidence of the study's inadequacies was so overwhelming that the journal in which it was published retracted it, providing this explanation from the editor and eliciting much commentary in the blogosphere. Seralini apologists have made numerous false and misleading claims about the retraction, but these have failed to persuade.

It must be noted that in citing the robustly discredited Seralini study Hansen illustrates a pattern he has followed throughout his public representations. Repeatedly he cites one or another from a small handful of studies published by well-known campaigners against biotechnology. In so doing he ignores the devastating criticisms they have received from the scientific community (peer review) as well as the vast body of accepted scientific literature contradicting their unverified claims. This pattern of advocacy is deemed to be scientific misconduct under widely accepted standards standards (see, e.g. http://www.ease.org.uk/sites/default/files/ease_guidelines-june2013-ethics.pdf [2]).

I then finally would like to say that in addition, we have no independent safety testing of these crops in the US because of intellectual property rights concerns. When farmers buy these crops, they have to sign a product stewardship agreement, which forbids them from giving such seeds to researchers. In 2009, 26 public sector scientists, took the unprecedented step of writing to the EPA and they protested that quote "As a result of restricted access no truly independent research can legally be conducted on many critical questions regarding the technology" end quote. That led the editors of Scientific American to publish a perspective that stated quote. "We also believe food safety and environmental protection depend on making plant products available to regular scientific scrutiny. Agricultural technology companies should therefore immediately remove the restriction on research from the end user agreements". We concur and believe that only truly independent safety test can give us answers about the safety of GE foods."

This claim is false, though there are some complicated issues involved here. The American Seed Trade Association has a policy in place to ensure research access to transgenic seeds,

[2] The relevant language: "None of our data presented in this MS has been fabricated or distorted, and no valid data have been excluded…Results of this study have been interpreted objectively. Any findings that run contrary to our point of view are discussed in the MS" At http://www.ease.org.uk/sites/default/files/ease_guidelines-june2013-ethics.pdf.

and Monsanto has made public a similar commitment . The public sector scientists who made the 2009 complaint cited above, in fact, had the access they sought at the time they made the unfounded complaint.

Furthermore, there has been an abundance of independent research over the years (see Nicolia et al., 2013, the GENERA database at BioFortified.org, and a massive compilation underwritten by the EU involving more than 130 research projects, covering a period of more than 25 years, involving more than 500 independent research groups, concluding "that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies… "

Finally at least 62 countries which together include more than half the world's population, including all the European Union, China, India, Japan, Korea, Australia, Russia, Brazil and South Africa, require labeling of engineered foods

The fact that other countries have labeling policies that lack a sound and scientifically defensible basis and mislead consumers about food safety is no justification for other countries to do the same. Homosexuality is illegal in at least 82 countries around the world. By Hansen's logic we should adopt similar legislation in the United States. But "If fifty million people say a foolish thing, it is still a foolish thing."[3]

and finally a number of polls from 1995 to 2011, have found between 78 percent and 95 percent of American polls support mandatory labeling. The New York Times came out with their poll that was at 95.

Poorly constructed polls, or those intended to deliver a specific result, are abundant. It is well established that if one asks a consumer "Do you want information X on the label?" the answer will overwhelmingly be "Yes." Consumers react with hostility to the suggestion that they might be deprived of information. But polls designed to measure what people think about food labels without being steered towards a specific conclusion find overwhelmingly that consumers approve of FDA's approach to labeling, and do not wish to see the inclusion of misleading information about biotechnology mandated.

Such labeling is important because consumers have a right to choose the foods they eat and to avoid any unintended health effects.

As established above, consumers already have multiple options through which they can choose to avoid foods derived from crops improved through biotechnology should they wish to do so. Proponents of mandatory labels have provided no data, nor any plausible hypothesis for a route to unintended health effects sufficient to justify the misleading labels

[3] Anatole France, quoted in Listening and Speaking : A Guide to Effective Oral Communication (1954) by Ralph G. Nichols and Thomas R. Lewis, p. 74.

proposed. Indeed, the campaign for mandatory labels itself is deliberately misleading as to the real intentions of those behind it. They say, for public consumption, that they believe labels are required to inform consumers and enable consumer choice, even though information is already abundant and consumers have multiple means to exercise freedom of choice. But the real objectives behind the campaign are to falsely stigmatise foods derived from crops improved through biotechnology as a means of driving them from the market. Proponents of mandatory labels have on occasion been honest in acknowledging these objectives .

And more recently

> **"mandatory labeling and bans, or GMO-free zones, should be seen as complementary, rather than contradictory."**

Consumers have a right not to be deceived and misled.

Yes I do believe it would pass constitutional muster. If you look at that particular case, the IDFA versus Amestoy. I know it very well because it was some of our testimony that helped get that bill passed in Vermont. And that was a bill that would require labeling of milk and dairy products from cows that have been treated with RBGH. And the problem with that bill, is the State didn't say it had any state interest. It said there was mere consumer curiosity. They would not admit that there could be for example any unintended health consequence. If there's an unintended health consequence, that's a compelling state interest and I would also point out that that decision was in 97. In 2010, there was the Sixth District Court outside of Cincinnati because in the state of Ohio they had tried to say, you can't label milk as RBGH free and the state indeed on appeal, the court ruled that yes, milk from treated cows is different and that labeling is valid. So I think that shows there's not a problem and I would also point out, what is pre-empted at the federal level, is ingredient labeling, so that's why this bill and the other bills that have been heard in other states are very clear not to say this is ingredient labeling. This is just the process of whether genetic engineering has been used. And so the FDA, they formally don't have a position on genetic engineering. So they can't really pre-empt these kinds of labeling.

Impartial legal authorities and settled case law overwhelmingly support the view that the labeling mandate advanced here by Mr. Hansen is unsound and constitutionally impermissible for multiple reasons. One clear example of this reasoning is found in a recent legal analysis made public by the Attorney General of the State of Hawaii. It is instructive to quote at some length:

> **This measure seeks to create state-specific labeling for imported genetically engineered produce. It is, however, subject to challenge and may be found unconstitutional for any one of three reasons.**
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> **First, pursuant to the Supremacy Clause of the United States Constitution, this measure may be found expressly preempted by existing federal labeling laws. Article VI, clause 2, guarantees that the laws of the United States are supreme and preempt those of the individual states.**
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> **Second, the Commerce Clause authorizes the federal government to "occupy a field" of regulation such that any state law in this area would be implicitly or field preempted. Article I, section 8, clause 3 of the United States Constitution, authorizes the federal government to regulate commerce to the exclusion of any state interference. Where the federal government has legislated in an area over which it has authority, any local efforts to do so, as is the case here, are likely to fail challenges to their constitutionality...**
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> **Last, state laws requiring specific information on food labels have been found to implicate the manufacturers' First Amendment right to free (commercial) speech. The State's effort to require labeling that is in conflict with federal labeling laws, is highly problematic.**

Congress, in creating the Federal Food Drug and Cosmetic Act ("FDCA"), empowered the Food and Drug Administration ("FDA") with the authority to create criteria for the labeling of food, which includes fresh fruits and produce. Section 403A of the FDCA expressly preempts inconsistent state labeling laws and provides that "[n]o subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce: (2) [a]ny requirement for the labeling of food of the type required by [the sections related to misbranded articles] that is not identical to the requirement of such section."

Section 403(a) of the FDCA prohibits the misbranding of food by utilizing a misleading label. Pursuant to its authority, the FDA has promulgated rules to implement section 403(a) and has created express labeling requirements. The FDA has also provided guidance regarding the labeling of GMO (genetically modified organisms, including produce) that strongly suggests that any state legislation requiring specific GMO claims will be considered "misbranding" and contrary to federal law. According to the guidance available on the FDA's website (current and most recently updated on May 22, 2009) the FDA's current position remains as follows:

> **The agency is still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act. FDA is therefore reaffirming its decision to not require special labeling of all bioengineered foods. In other words, the FDA has considered the matter, has no concerns regarding the risk to public health such that a failure to "warn" the consumer of the presence of genetically modified material would constitute a misbranded food, and thus does not require GMO-specific labeling. Therefore, any state requirement to do so would violate the comprehensive federal scheme of food labeling laws.**

…where, as is the case here, the FDA has expressly considered an area of regulation (GMO food labeling) and has declined to make it a requirement, the states are said to have been implicitly preempted from doing so. The Supreme Court has illustrated this principle very clearly in Gade v. National Solid Wastes Mgmt. Ass':

> **We hold that nonapproved state regulation of occupational safety and health issues for which a federal standard is in effect is impliedly preempted as in conflict with the full purposes and objectives of the OSH Act.... The design of the statute persuades us that Congress intended to subject employers and employees to only one set of regulations, be it federal or state, and that the only way a State may regulate an OSHAregulated occupational safety and health issue is pursuant to an approved state plan that displaces the federal standards. 505 U.S. 88, 98-99 (1992) (citation omitted).**

A court, applying the same principle of field preemption to the question of whether the federal government has occupied the field of GMO food labeling or food labeling more broadly, would likely conclude *that the FDA has developed a federal standard for GMO food labeling* (by not requiring any) *that no state can interfere with* in the same way that the Occupational Safety and Health Administration has set a federal standard for worker safety.

…Finally, it should be noted that a federal appellate court has struck down a state food labeling requirement on First Amendment grounds. In International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996), the Second Circuit Court of Appeals upheld a challenge to Vermont's requirement that dairy farmers label milk produced from cows treated with growth hormones. After dairy farmers argued that the state should be enjoined from violating their right to free speech and also challenged the state law on the basis of the Commerce Clause, the court struck down the law on First Amendment grounds without even addressing the implications of the Commerce Clause. Id. at 70. The court applied the 4-prong test for state restriction of commercial free speech developed in Central Hudson Gas and Electric Corp. v. Public Serv. Comm., 447 U.S. 557 (1980), whereby one must determine:

(1) whether the expression concerns lawful activity and is not misleading;
(2) whether the government's interest is substantial;
(3) whether the labeling law directly serves the asserted interest; and
(4) whether the labeling law is no more extensive than necessary. International Dairy at 72 (citation omitted).

The court asserted: "The State of Vermont bears the burden of justifying its labeling law ... [a]s the Supreme Court has made clear, [t]his burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." Id. at 72-73 (quoting Edenfield v. Fane, 507 U.S. 761, 770–71 (1993)). Particularly relevant to a review of this bill, the court concluded that, "Vermont has failed to establish the second prong of the Central Hudson test, namely that its interest is substantial. International Dairy at 73. This decision demonstrates that a court, in its review of a state labeling requirement that otherwise appears to serve a legitimate state interest, will nevertheless apply fairly rigorous scrutiny and demand that the reason given be valid and demonstrable. This measure arguably fails this test because the FDA has made its own inquiry and determined that there is no scientific (health and safety) or consumer (misleading or misbranded product) foundation to require a GMO label on food. Consequently, this measure may be preempted by federal law or be found an impermissible restriction on commercial free speech.

ASSEMBLY MEMBER DINOWITZ: So you're saying that the FDA has neither said genetically engineered foods is bad or good? They simply haven't taken sides yet?

HANSEN: Well what they did is, in 1992, they said it's an extension of conventional breeding. Therefore we're going to treat it the same under the law but then what they did in 2001, is with this premarket biotech notification. They actually put out a statement saying, genetic engineering is different because of this insertion or mutagenesis, they would want data on each separate transformational event. But they're continuing to regulate under the '92 policy, not the 2001 policy and I would argue, that the 2001 policy is them admitting that they got it wrong in 1992 and again, globally there's an agreement that genetic engineering is different. And the reason that's important for Codex is cause that's functionally written into the WTO agreements.

ASSEMBLY MEMBER DINOWITZ: I'm sure you read the front page article in Sunday's Times on the potential destruction of the Florida Orange Crop. Do you have any thoughts on that?

DR. HANSEN: Yeah I thought that was an interesting article. Although, what upset me about it is, it didn't talk about any alternatives that citrus greening disease is being vectored or it's a bacteria and what's causing it to infect the citrus trees. It's a little insect called the Asian citrus psyllid and it turns out that that insect normally comes from Asia. They found a parasitic wasp that perfectly controls this disease in the Reunion Islands and in Puerto Rico there have been releases in Florida that haven't worked that well yet but that's cause they think that there's a genetic strain of parasitoid that maybe that's the problem. But the bottom line is there's a biological control, that is working that more money could be looked at and that's not mentionedat all in the article. That is that there's another way to treat that same problem. It has cured the problem as I said in other countries and there could be further work done here.

And there was actually the week before this article on how we need engineered potatoes and the problem with that article is it didn't mention these other agro-ecological techniques, to get to the same endpoint.

ASSEMBLY MEMBER DINOWITZ: ...and the release of those wasps and that other locations hasn't caused any unintended consequences?

HANSEN: No in fact the scientists that had been doing some of the releases here, DR. Marjorie Hoy and colleagues. She's a good scientist at the university of Florida. She actually did some of the first work on genetically engineered spider mites. So they're looking for these methods and I have a review article from last year about the greening disease and how many places do think these parasitories and natural enemies are useful in the management of the insect that vector's the disease. And so when you're spraying all the time, you're killing all those natural enemies, so we need to pay attention to some of that natural ecology because with the greening, we don't know whether that's going to work down the work. They spent millions on it and yet there're these wasps that have worked in other countries. If only some of that same money could go into finding the right strain. We could probably get it to work here as well.

ASSEMBLY MEMBER LINDA B. ROSENTHAL: … I'd like to ask Dr. Hansen, I know you've been travelling for years around the world, basically testifying and providing your expert opinion GMO's and GMO labeling. Can you tell us some more about your assertion that independent research can't be done on this genetically engineered crops and that researchers have to get permission from the companies, before doing any of the research?

HANSEN: Yeah that's one of the huge problems. Since these have utility patents, the companies control them, so any research you want to do with them, there is an agreement that you have to come to with the company. That's why you know when farmers buy the seed, it says in their technology agreement, they can't even give the seed to researchers. The only way the researcher can get it, is they have to go to the company. And I should have brought it here with me but just last week there was an article, it was the Connecticut News Junkie and it was about labeling and what's happening in Connecticut and all the States in the North East and the Monsanto spokesperson there, said these are the most heavily tested products but they said because they're patented, there are no independent safety test and that's what the real problem is. I said you know that's why all those scientists wrote to the EPA and that's why if you look at it, most of the independent safety testing that is being done, they've all been studies that have been done outside the US.

As noted above, these claims are false and misleading.

Cause I can actually give you examples. I know scientists here in New York City, for example who did work showing that BT, that the endotoxin flows out of the roots of the plant and can actually adversely affect soil organisms. So they found it for one Monsanto variety and when DR. Gzowski (ed – refers to Gunther Stotzky) went back and said I would like to test it on these other varieties, Monsanto said sorry, we don't agree with your research, so we're not going to give you access. So he had to stop that work and move to something else. So that's a real problem because the way I put it is where would we be today if the tobacco companies got to control what kind of research gets done. That should be unacceptable particularly for health and safety any scientist should be able to take these foods and do whatever they want with them in terms of scientific justification and that's why I think there's a real problem because we need independent science.

Hansen seems to refer here to the work of Prof. Gunther Stotzky, a microbial ecologist at NYU. His description of Stotzky's work is not accurate.

Stotzky investigated the potential for Bt proteins to impact organisms living in soil. He showed that exposure to Bt in the soil had no impacts on a range of organisms. Initially, Stotzky had been concerned about possible Bt residues in the soil because his early work suggested they were secreted from the roots of Bt plants into the soil. His subsequent research confirmed for himself and other skeptics that if effects were present they were transient and not related to Bt proteins. See Fate and effects of insect-resistant Bt crops in soil ecosystems. An excerpt from the abstract:

It is crucial that risk assessment studies on the commercial use of Bt crops consider the impacts on organisms in soil. In general, few or no toxic effects of *Cry* proteins on woodlice, collembolans, mites, earthworms, nematodes, protozoa, and the activity of various enzymes in soil have been reported. Although some effects, ranging from no effect to minor and significant effects, of Bt plants on microbial communities in soil have been reported, using both culturing and molecular techniques, they were mostly the result of differences in geography, temperature, plant variety, and soil type and, in general, were transient and not related to the presence of the *Cry* proteins.

ASSEMBLY MEMBER ROSENTHAL: So in the absence of those kinds of tests, your opinion on labeling as a second best?

HANSEN: Yes we label it and that's the global language that was gotten through Codex's labeling serves as a risk management measure, to deal with scientific uncertainty. And the scientific uncertainty, there's uncertainty in the genetic engineering process 9 itself. You have no control over where you're inserting things, so you can disrupt stuff and cause all sorts of problems. So it's unknown what the health consequences should be. That's why you label. Because if something shows up down the road, that's the only way you can track it cause none of us are saying that these foods are unsafe enough that people are going to be dropping over you know and acutely dying tomorrow. It's the long-term effects. So that's why you have to have labeling to be able to track that.

ASSEMBLY MEMBER ROSENTHAL: And just if you would briefly say, in all the other countries that do demand labeling, how do they deal with that?

HANSEN: Well, there's actually different forms of labeling in the different countries. So for example for the European Union, they require everything to be labeled. If there's more than nine tenths of a percent of any ingredient is engineered, that fact has to be on the label. They also require labeling even if you can't detect any engineered protein or DNA. And what that means is oil from engineered Canola or engineered soy beets would have to be labeled. Sugar from engineered sugar beads has to be labeled, so that's one form. That's how Europe and China does it.

Other countries like Japan and Australia, they say you test, if you can detect this transgenic material. you test, and then they have various thresholds - one percent or two percent. So it varies like that and then some countries label it on the ingredient on the back. Others for example, Brazil has a triangle with a T in it. That stands for transgenico. So there's different labeling schemes in different countries.

ASSEMBLY MEMBER ROSENTHAL: And do companies like Monsanto work over there to try to you know get rid of these labeling requirements or have they conceded the battle in those countries?

HANSEN: Well what's actually interesting is when the European Union required labeling over ten years ago, Monsanto actually took out advertisements in both French and in the United Kingdom saying that they supported labeling. That there was going to be this new labeling regime coming in and that they supported it.

These claims are false. It is a matter of historical record that Monsanto has never supported mandatory labels of the sort Hansen favors, neither in the United States, Europe, nor anywhere else in the world. Consistent with its support for voluntary labeling, Monsanto ran ads in United Kingdom in the 1990's to support the voluntary efforts of retailers to provide information they believed would be of interest to their customers. Further details can be found here.

ASSEMBLY MEMBER ROSENTHAL: And so what happened...

HANSEN: So in terms of working against it, the way that happens is it's the US that hasn't supported labeling so the pressure would come on you know bilateral agreements and that way. So that's how the companies would be working on that front.

ASSEMBLY MEMBER ROSENTHAL: ...but why did they say ten years ago they supported labeling abroad? And I guess we can...

HANSEN: Because the public in Europe wanted that, frankly. … I mean that's why we have now. There's 64 countries around the world that requiring labeling and new ones come in every year. Just this year for example, India is the newest country. Their labeling started in January.

ASSEMBLY MEMBER ROSENTHAL: And the fact the FDA has basically sat on the sidelines it seems to me is actually aiding and abetting the anti labeling push by those companies?

HANSEN: Well I think what the big problem is, is you know, it's 20 years later and we have global agreement. Genetic engineering is different than conventional breeding. There should be required safety assessments. US cannot meet that standard. We can't meet the global standard, the US knows is. Behind closed doors they admit that. So we have to get some kind of safety assessment and until we get that, we have to have labeling.

Now the engineered animals that might be on the market, like the salmon, they're going to require data but the first data package is very poor with that one.

These assertions, again, are either false or misleading.

Global agreement among scientists holds that the tools of biotechnology/recombinant DNA are extensions of conventional plant breeding, using tools and techniques directly derived from our understanding of ubiquitous natural phenomena; and that the potential hazards of crops and foods improved through biotechnology are the same as those with which we are already familiar in other foods.

In the United States, safety assessments for field trials or commercial plantings of all biotech crops are mandatory. EPA review and regulation of all plantings of biotech plants incorporating pesticidal compounds is mandatory. Premarket risk assessment and evaluation are mandatory for all foods derived from bioengineered animals. All foods derived from

bioengineered plants MUST be safe to be allowed on the market, and this requirement is unaffected by the fact that the FDA consultation process is *de jure* voluntary, but *de facto* mandatory; and this is corroborated by the fact that every single bioengineered plant derived food or feed has gone through the consultation process, as shown here.

[More recently, Mr. Hansen has cited a statement with "90+" signatories asserting the absence of scientific consensus on the safety of foods derived from crops improved through biotechnology. This assertion presents no new arguments or data, and ignores the staggering mass of studies already cited demonstrating the safety of these foods, as well as their unblemished safety record. Instead, it recycles such discredited claims as those of Seralini, Carman et al. (for additional critical analyses see www.AcademicsReview.org). It is worthwhile therefore to note that the group behind this press release is comprised of individuals with a long history of opposition to agricultural biotechnology that relies on ignoring or distorting reality. Indeed, the group is merely one element in a campaign that has "propagated claims that the biology is unclear despite the fact that the science is far more settled on GM foods than it is on climate change. One blogpost has dismissed them with these words:

> **" A group of 93 "scientists have signed a letter saying "GMO is bad…" They did so in response to a roundup of more than 2000 actual studies, almost all done over the last decade, that have failed to produce any evidence that GMO is anything other than plain old food, and some of the safest food we consume.**
>
> **"Forget who they are (they are largely nobodies, often from unassociated fields, and all with past anti-GMO agenda) but… 93? …Even 9-11 truthers were able to get more than 2000, architects and engineers to sign their loony position. You don't want to know how many nut-jobs still believe they can challenge the scientific consensus on Climate Change and Evolution based on wishful thinking and petition.**
>
> **"Scientific consensus is not done by opinion poll, nor is it done by petition (though if it were these "dissents" would all fail due to the hasty generalisation fallacy). The scientific consensus is a consensus of data, is born out by peer reviewed study and published work. Thus a meta analysis of a topic is a perfect way of determining consensus. The consensus, by the way has stood for decades. GMO is not only as safe as any other food, it is provably so (most other food never having been tested) and in fact it is simply food, not magic."**

Another blogpost has dissected such claims in detail, with similarly devastating results. The Australian Agricultural Biotechnology Council reaffirmed this judgment, and further showed

that European agriculturalists are keen to adopt the technology, and increasingly dissatisfied with the innovation stifling and scientifically indefensible European regulatory regime.

> **"ABC chair Julian Little said the statement had been put together by an anti-GM group and he insisted that contrary to the claims, there was an "overwhelming weight of evidence" that points to the safety of GM crops. Dr Little said: "Biotech crops are among the most extensively tested foods in the history of food safety.**
>
> **"In 2010, the European Commission concluded on the basis of 130 research projects involving 500 independent groups over 25 years that 'there is, as of today, no scientific evidence associating GMOs with higher risks for the environment or for food and feed safety than conventional plants and organisms'.**
>
> **"This year, the representative body of the national science academies of the EU Member states agreed, saying that 'there is no validated evidence that GM crops have greater adverse impact on health and the environment' than any other crops produced using plant breeding techniques."**
>
> **"Dr Little added that an estimated three trillion meals containing GM ingredients have been eaten around the world over the past 13 years "without a single substantiated case of ill-health".**
>
> **"The World Health Organisation (WHO) has said that: 'No effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved'."**
>
> **"Dr Little said the WHO's statement was backed up by government regulators around the world, including the Food Standards Agency (FSA) in the UK.**
>
> **"The Agricultural Biotechnology Council (ABC) of Australia said the ENSSER's statement "flies in the face of a consenus of an overwhelming majority of scientists".**
>
> **"Every legitimate scientific organisation that has examined the evidence has arrived at the conclusion that GM crops and the foods they produce pose no risk to human health or the environment beyond those posed by their conventional counterparts," added ABC Australia.**
>
> **"Meanwhile, EU farming groups, including the NFU, NFU Cymru, NFU Scotland and the Ulster Farmers' Union (UFU), have added their name to a different letter, which voices "deep concern" about the effects of GM policies and regulations in the EU.**

"In an open letter sent to the European Commission on behalf of the French Association for Plant Biotechnology (AFBV)[and 13 other groups], they called for better for access to the best crops, including GM varieties, so that agriculture in Europe can be more sustainable and less reliant on imported products. The letter states that the lack of options for GM technology available to farmers in Europe can equate to significant loss of income and a missed opportunity.

"Helen Ferrier, NFU chief science and regulatory affairs adviser, said: "The heads of EU institutions have a great deal of power to sort out this mess and ensure the EU doesn't become uncompetitive in both agricultural production and scientific research.

"This letter demonstrates the strength of feeling in the agriculture sector across Europe. Swift action must be taken."]

ASSEMBLY MEMBER ROSENTHAL: So I mean it seems that the state by state mandatory labeling laws, is the way to go in the absence of FDA?

HANSEN: Yes in the absence of the FDA taking it, I think states have to take strong action cause that's often how you get federal action, is action that we take in a few states and then it often moves to the federal level. So when the federal government won't take action, it's up to the states to lead and this has happened before, in New York and California and other states have led before and I think they need to lead again.

The premise here is demonstrably false. Hansen's dislike of FDA's findings and policies does not alter the fact that FDA has been engaged and active over many years considering, deciding upon, and implementing policies and regulatory oversight that are consistent with the findings of science and recommendations of scientists.

ASSEMBLY MEMBER DENNIS H. GABRYSZAK: Thank you just a couple of questions relative to the FDA. FDA labeling right now of products, is that done or controlled by the FDA?

DR. HANSEN: Some labeling is. But others, for example if you want to put say your New York cheese, you don't have to get that...

ASSEMBLY MEMBER GABRYSZAK: Well I'm not talking about the ingredients you know, if the product right now...

DR. HANSEN: Yes FDA controls ingredient labeling.

ASSEMBLY MEMBER GABRYSZAK: Do states individually have the opportunity to...or are there any states currently that add to that federally approved labeling?

DR. HANSEN: We have the State of Alaska passed a mandatory labeling bill for any fish that are engineered, would have to be labeled in Alaska. That was passed a few years ago and has not been

challenged as being unconstitutional. So there is a mandatory labeling law in one of the states that's been enacted. It just hasn't come into force because this engineered fish still hasn't been approved yet.

ASSEMBLY MEMBER GABRYSZAK: One thing is I can agree with you, whether it is the fact that there still needs to be additional testing in terms of determining what's good or what's bad about GMO's. I do agree with that. You've stated that under the independent safety testing, that a company can deny a research scientist or someone from getting the seed or the crop and doing independent testing on that?

HANSEN: Well absolutely. Whether it's safety testing or environmental testing. That's why those scientists wrote to the EPA because for example if a scientist wants to compare Monsanto's BT corn root worm variety right next to Syngenta's, they can't do it. That's why they complained to the agency and there have been some changes but no there is not this independence and that's the big problem.

ASSEMBLY MEMBER GABRYSZAK: Is there any testing that is done by the FDA on these products?

HANSEN: No, there's none.

ASSEMBLY MEMBER GABRYSZAK: The FDA doesn't get samples, doesn't get seed. They don't provide any type of testing before that seed goes to be sold or a product goes to market?

HANSEN: No the only thing they do is these voluntary safety consultations and that's like a shadow play because if you look at the letter that goes to the agency, that the agency sends to the company afterwards, there's no conclusion. I mean here's the sentence for example that was sent to Monsanto in their letter on September 25th 1996 and it was about Mon810 the first BT corn variety and I'm going to read you the sentence and then this sentence is actually in all 97 consultation letters. Quote, "based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that corn grain and forage derived from the new variety are not materially different in composition safety, or other relevant parameters, from corn, grain and forage currently on the market and that they do not raise issues that would require premarket review or approval by FDA." end quote. So the FDA is very clear, they make no conclusions about the safety. They could have put in a sentence in their letter saying we agree with this analysis but they say nothing and I think the reason for that is their lawyers know this is not a safety assessment. So if something goes wrong down the road, these companies don't have any liability protection.

ASSEMBLY MEMBER GABRYSZAK: So the FDA sets up no requirement as far as...

HANSEN: None whatsoever.

ASSEMBLY MEMBER GABRYSZAK: ...GMO's?

HANSEN: That's why we're saying there should be, not only required safety assessment but then you can start to talk about the protocols of what kinds of tests should actually be done. So anything that the companies are doing, they get to decide themselves. And we don't think that that is not [phonetic] the proper way... anything that we put into our food it should not be up to companies independently to determine whether that's fine or not. That has to be made by an independent authority such as the FDA.

ASSEMBLY MEMBER GABRYSZAK: ...based on what you just said, the FDA does no testing of GMO's before it goes in?

HANSEN: That's correct.

Hansen's response here is artfully worded, but misleading to the point of deceit. It is true that FDA does no testing themselves. FDA decided that the costs and responsibility for ensuring the safety of foods placed on the market should be borne by those who stand to profit thereby, rather than being subsidized by taxpayers. Is Mr. Hansen suggesting that taxpayers should subsidize the regulatory costs Monsanto, Syngenta, and DuPont, and other companies incur while demonstrating the safety of products they hope to bring to market?

It must again be pointed out that the requirement that bioengineered foods placed on the market be safe is absolute.

The guidance FDA has put in place to ensure safety, as required, is based on more than a decade of work by expert groups who laid out very clearly what questions should be asked and how they should be answered to ensure safety. These questions are lengthy, detailed, and publicly available, having been adopted through Notice & Comment Rulemaking procedures that provided Mr. Hansen, and all people, numerous opportunities to provide input and suggestions.

Mr. Hansen implies that the absence of a *de jure* requirement by FDA that bioengineered foods be subjected to the consultation process means there are doubts about the safety of the foods that have gone through the process voluntarily. This is not the case. The assertion further ignores the fact that the very same foods have undergone mandatory evaluations by regulatory authorities in Canada, Australia, New Zealand, Japan, Korea, Brasil, Europe, and elsewhere, and that in all cases the results of those mandatory evaluations are identical to those resulting from FDA's "voluntary" process.

ASSEMBLY MEMBER GABRYSZAK: The FDA website says FDA regularly regulates the safety of foods and food products from plant sources, including food from genetically engineered plants. Foods from genetically engineered plants must meet the same requirements including safety requirements as foods from traditionally bred plants.

HANSEN: Right.

ASSEMBLY MEMBER GABRYSZAK: And also evaluating the safety of food from a genetically engineered plant, is a comprehensive process that includes several steps… This was coming from...

HANSEN: I know. But notice they don't make any conclusion and they say they have to meet the same requirements as any conventionally bred food and you can put a new variety of tomato or anything you want on the market and not do any safety testing at all. There's no requirement. So when they say that all these tests are being done, they're not being evaluated by the FDA. The FDA, they don't make a conclusion about any of this. They do more work for a color you want to add to a food or any tiny food additive. Before you can put that into a food, it has to meet the legal criteria's reasonable certainty of no harm. That's all we're asking for these engineered things and whatever the FDA says there, they don't make any conclusion. They don't require anything. All they say is the companies do a bunch of these tests and they think this is fine. And that's ot--and we would not allow that with food additives. We wouldn't allow it with colorants. Why are we allowing it with GE when everybody in the world agrees that it's different and once it's different and it raises safety issues, then you test it and you label it.

ASSEMBLY MEMBER GABRYSZAK: Being from Consumer Reports, I think this will also be my last question now. Being from Consumer Reports and in terms of the labeling, is there a recommendation that you would have? Is it something that would just be included in the current label?... What would you say would be appropriate in terms of what kind of labeling do you want...

HANSEN: The labeling would be different… if it were done on a federal level versus at the state level because as I said at the federal level, they controlled ingredient labeling. So this could not be required that ingredients all have to be labeled. That might be a better way to go but that's why all these bills, what they do is they require that if there's any genetically modified organisms or parts of any genetically engineered products in there, that statement has to be on a label. If it's going to be on the front or the back, it's all up to what people want to do. We would just like to see at the state level, just the fact that it's engineered, it should be somewhere on the label cause that's the first step for being able to track any problems. If we were talking about a national bill, then I might talk about what kind of ingredient labeling should be done but that's not what's under discussion.

ASSEMBLY MEMBER GABRYSZAK: I'm sorry I just prompted one question when you talked about, leaving it to individual states for labeling. If you had individual states that pass whatever type of requirement for labeling. Be it an additional set aside label or include I don't know would you be able to include it in the ingredient label that's on products right now? If that was to be done, what would the impact be upon the industry that produces these products, in terms of production or whatever, then you have to...

HANSEN: Oh yeah the problem with the various states. Well all I can say is what's being done there. I've testified so far in all the states in the North East where bills have moved through. We've worked and so have Centre for Food Safety and others has tried to make sure that the legal language in all those, is functionally the same and that's also true with the ballot initiative out in Washington State. So the idea on all these things as to make them as easy to implement as possible, to make all the state ones be basically the same thing, so that you don't have this patchwork quilt and one State wants you know one percent threshold and another state wants five percent and another state. That would create a nightmare but if everyone is trying to do the same thing then I don't see where the problem is cause if you can label it for one state, you can label it for others.

ASSEMBLY MEMBER GABRYSZAK: Thank you.

ASSEMBLY MEMBER DINOWITZ: Assembly member Simanowitz.

ASSEMBLY MEMBER MICHAEL A. SIMANOWITZ:

Two real quick questions. Number one, if you know of none organically labeled products, what percentage of products in the market contain GMO's?

HANSEN: For the none labeled, the percentage that would be engineered is, it should be pointed out for soy beans, 94 percent of the acreage is engineered corn 88 percent of the US acreage is engineered. Corn and Soy are in about 75 to 80 percent of all processed food products, so that's what your, that's roughly what you're talking about.

ASSEMBLY MEMBER SIMANOWITZ: So is it safe to assume that if I walk into a grocery store and I'm not buying organic, that the product that I'm buying contained some sort GMO?

HANSEN: If it's processed food and it contains corn or soy. Yes it probably has it but in terms of whole things, the only other whole foods that are out there is about, as of 2006 there were 11 percent of zucchini acreage and then from Hawaii we've got some papayas but other than that, there's not much that would be fresh fruits and vegetables.

ASSEMBLY MEMBER SIMANOWITZ: So purely from a marketing standpoint, wouldn't it make sense to label foods that it's GMO free?

HANSEN: Well no, that's being you both have organic in there's the non-GMO project and they have 5000 or 6000 products now labeled. The problem with that, that's fine and you know that's a market advantage but if you're talking about a potential unintended health consequence because there wasn't proper safety assessments, you want to know who is exposed. So that means you want to know that's why you have to have a mandatory label because if something doesn't have a label on it, it could contain an engineered ingredient or it couldn't. The way you have to track those problems to do proper epidemiology's you need to know who is exposed and that's why you have to have a label. It's to track any unintended health consequence. Either positive or a negative that could pop up. That's why having the market work and just have this voluntary labeling you know, GE-free labeling, that's fine if the market wants to do that but that doesn't help you with the tracking of potential safety concern.

As documented above, there is no credible hypothesis to support any assertion of novel or unknown risk; indeed, billions upon billions of meals consisting entirely or in part of foods derived from crops improved through biotechnology have been consumed over the past two decades without a single example of so much as a sniffle resulting. Without exception, every single claimed injury from eating "GM" foods has failed to withstand scrutiny.

It would be interesting to see a tally of the deaths that have taken place over the same interval from consumption of organic foods carrying foodborne pathogens, the recall notices and news reports of which are alarmingly routine.

But the assertion that labels of the sort Hansen supports are required to enable the tracking of "any untineded health consequence" fails, like Hansen's other assertions, to withstand scrutiny. There are several fatal flaws.

First, labels of the sort proposed would not apply to a large proportion of food eaten every day by consumers. Fifty percent of food dollars are spent on restaurant or prepared foods that would be exempt.

Second, labels of the sort proposed would lump as many as two hundred distinct "GM" crop types under one label, with no provision to identify, much less track, which components from which varieties might be present in any particular processed food. If one or another of these were in fact to be involved in an unexpected adverse eventthe label proposed by Hansen would provide no way to identify or trace which ingredient was responsible.

Furthermore, the "GM" label would be applied to products containing more than 0.9% of any fraction of material derived from any crop improved through biotechnology. Thus biotech crop-derived pure sugar, soybean and other oils, lecithin, HFCS, starch, tocopherol which are as pure as, and indistinguishable from, their industrial chemical or conventional crop counterparts, would require a mandatory label on a product even though there is no conceivable mechanism by which they could be the offending component. Thus if a subject were to report that they had eaten products labeled GM it would mean nothing because the source and the nature of the consumed material would still be unknown,

And finally, the most important reason why mandatory labeling would not help traceability or epidemiology is that people generally are very vague about what they ate in the last 24 hrs let alone the last few days or weeks before they became ill. There is a rich literature in the nutrition survey business on how to figure out what people really ate because self reporting is so unreliable. It may seem hard to believe but you can actually show products to people and ask them if they have consumed the product in the last day or week and the odds of getting a correct answer aren't much better than 50-50--the frequency of a coin toss or a guess.

If there were mandatory labels, perhaps 90 or 95% of the US population might have consumed "GM" foods. What could it conceivably tell an epidemiologist if 1% of the population was suffering from some strange new malady but 95% of the population had eaten "GM" foods? Well, one conclusion would be the malady cannot be attributed to "GM"

crops and with regard to the "GM" foods on the market to date, that would be a correct conclusion.

Thus if one were trying to trace a mysterious illness and were working on the hypothesis that a "GM" crop was the root of the problem it would be impossible to use mandatory labels to provide any meaningful insight. Fortunately, as the data show, "GM" crops pose no new or different risks, and are as safe as or are safer than crops produced by any other type of breeding.

ASSEMBLY MEMBER SIMANOWITZ: And are there any other states and they may not be able to but are there any states that deal with or regulate the safety standards for GMO's, that legislate testing or?

HANSEN: No.

ASSEMBLY MEMBER DIDI BARRETT: Thank you. You know I appreciate what you were saying about unintended consequences but I represent a District with a lot of small and mid-sized family farms in the Hudson Valley and you know we're in this really tough economic times. It's been one of the great success stories that agriculture and small family farms are coming back. Young farmers are literally putting down roots in the area but now I'm concerned about what the ramifications, the unintended consequences to some of these farms. When you said just earlier that you know 90 percent of soy already is genetically modified. I mean what's available? I hear from farmers that even as much as they'd like to be feeding their animals feed without GMO's that it's not even available for them. So what do we do about that? How do we address that...

HANSEN: Yeah there is increase market demand for non-engineered feed but I should point out that your farmers that are concerned that they're feeding their cattle engineered corn or soy, this labeling doesn't apply to them because this is only labeling for foods that are engineered. So an animal that has eaten an engineered corn or soy, that animal isn't engineered anymore than you're engineered because you've eaten corn or soy. So that doesn't get labeled.

HANSEN: No the only they would be required to be labeled is if and when they decide to approve a genetically engineered fish or a pig or a cow or an animal but no just feeding feed to those animals does not make them genetically engineered.

ASSEMBLY MEMBER JAMES SKOUFIS: Thanks for your testimony and before I ask my one or two questions, let me just say that I voted for this in committee this bill but I had a lot of reservations. I was looking forward to this public hearing. You mentioned a lot of things in your testimony that don't pertain to this bill though. You mentioned what the FDA did and didn't do. This bill is not about who can research on the seeds, which I think you know scientists should be able to do the research on the seeds but that's not what this bill addresses. The health risks of genetically modified food, this doesn't address. This isn't

a conducted study into the health risks of GMO's, this just has to do with labeling. So I want to focus on that and my first question is the 1992 FDA decision, what went into that decision? Did they do studies? Did they do any kind of research in coming to the conclusion that there was no substantive difference between genetically modified foods and traditional foods?

HANSEN: No there's actually a lot of debate within the agency and their policy that came out looked remarkably, virtually identical to one that had been drafted for the International Food Biotech Council, a couple of years before in 1990. In fact, if you look internally, the head of the centre for veterinary medicine at the time Gerald Guest actually wrote a letter to the FDA saying since animals could be eating corn or soy's engineered, that's the main thing in their diet. The Centre for veterinary medicine said that should be required safety assessments of these foods before they go onto the market and they weren't listened to. There were other scientists within the agency that said genetic engineering is different. It could raise these problems but they were overruled at the top and it was decided that there wasn't any difference. This was a policy that came out of the Council on Competitiveness in the White House and it was introduced by then Vice President Dan Quayle as a deregulatory initiative at a biotechnology industry organization gathering on May 29th 1992.

ASSEMBLY MEMBER SKOUFIS: So on the opposite side, are there any studies that have shown that there are significant or really any health risks from genetically modified foods?

HANSEN: Yes, there are quite a range of them. There's dozens and dozens of... ...that have been done anywhere from allergenicity to adverse reproductive effects to effects on the gut. These are very carefully well designed studies and those can all be presented. The reason I mentioned health effects, is that's the reason why you label. Labeling as I said serves as a risk management measure to deal with scientific uncertainty. That's clearly the case here and so that's why I would argue we have to label these foods so that we can track them.

As noted above, Mr. Hansen repeatedly cites one or another from a small handful of studies published by well-known campaigners against biotechnology. In so doing he ignores the devastating criticisms they have received from the scientific community (i.e., peer review) as well as the vast body of accepted scientific literature contradicting their unverified claims. This pattern of advocacy is deemed to be scientific misconduct under widely accepted standards (see, e.g. http://www.ease.org.uk/sites/default/files/ease_guidelines-june2013-ethics.pdf [4]).

As demonstrated repeatedly in quotes and citations provided above, regulatory officials and independent scientists around the world are united in their considered professional

[4] The relevant language: "None of our data presented in this MS has been fabricated or distorted, and no valid data have been excluded…Results of this study have been interpreted objectively. Any findings that run contrary to our point of view are discussed in the MS" At http://www.ease.org.uk/sites/default/files/ease_guidelines-june2013-ethics.pdf.

judgments that those studies held out by Hansen and his fellow professional opponents of ag biotech to support the charge of potential health risks from bioengineered foods have been, without exception, fatally flawed, usually in multiple ways.

A summary of the more prominent and egregious of these, aside from the Seralini debacle documented above, can be found at www.academicsreview.org . As noted repeatedly, and stated most clearly perhaps by the American Medical Association in their recent statement, "…the FDA's science-based labeling policies do not support special labeling." The American Association for the Advancement of Science recently reached a similar conclusion, stating

> **There are several current efforts to require labeling of foods containing products derived from genetically modified crop plants, commonly known as GM crops or GMOs. These efforts are not driven by evidence that GM foods are actually dangerous. Indeed, the science is quite clear: crop improvement by the modern molecular techniques of biotechnology is safe. Rather, these initiatives are driven by a variety of factors, ranging from the persistent perception that such foods are somehow "unnatural" and potentially dangerous to the desire to gain competitive advantage by legislating attachment of a label meant to alarm. Another misconception used as a rationale for labeling is that GM crops are untested.**
>
> **… The World Health Organization, the American Medical Association, the U.S. National Academy of Sciences, the British Royal Society, and every other respected organization that has examined the evidence has come to the same conclusion: consuming foods containing ingredients derived from GM crops is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques.**
>
> **… contrary to popular misconceptions, GM crops are the most extensively tested crops ever added to our food supply. There are occasional claims that feeding GM foods to animals causes aberrations ranging from digestive disorders, to sterility, tumors and premature death. Although such claims are often sensationalized and receive a great deal of media attention, none have stood up to rigorous scientific scrutiny. Indeed, a recent review of a dozen well-designed long-term animal feeding studies comparing GM and non-GM potatoes, soy, rice, corn and triticale found that the GM and their non-GM counterparts are nutritionally equivalent.**
>
> **… The FDA does not require labeling of a food based on the specific genetic modification procedure used in the development of its input crops. Legally mandating such a label can only serve to mislead and falsely alarm consumers.**

ASSEMBLY MEMBER SKOUFIS: Well the reason why I asked those two questions was, isn't it FDA policy already that if they're in genetically modified food, that if there is something that's introduced. That causes a new allergy. Doesn't that already have to be labeled? Isn't that FDA policy already?

HANSEN: No what the FDA policy is if any of eight, what they call the eight major allergens. If they've been moved into something, yes but if something has increased the level of a known endogenous allergen, no that doesn't require anything and I would point out there is, as I've submitted in testimony elsewhere, there is a study where they looked at Mon 810 and it's near isoline. They were grown in a growth chamber, so it's exactly the same environment. Well it turned out that the Mon810, it had a gene turned on in it that was gamma zein. That's a known corn allergen. So we have an example of a known allergen in corn was turned off in the wild type and turned on in the engineered one.

Mr. Hansen does not provide a citation to support these claims, but similar claims have been made in a paper by Fonseca et al. in 2012. This paper does not support Hansen's claims.

To be specific: Fonseca et al report that IgE samples were purchased from Plasmalab international. They are NOT documented by a clinical food allergist as from patients with food allergies to maize. The authors of this paper claimed histories of maize allergy and a modest serum IgE ImmunoCAP level solely on the basis of lab testing by Pharmacia (Phadia, now ThermoFisher), a lab with a history of finding high frequencies of positive IgE signals. Such findings are necessary, but not sufficient to demonstrate a food allergy. Such false positives are well known to result from IgE reactivity against proteins commonly found in pollen and elsewhere, including irrelevant cross-reactive carbohydrate determinants. Furthermore, their study involved only 2 plasma samples (2 individuals). The authors concluded that there is no real difference in GM vs non-GM allergenicity based on IgE binding. They did report, from a sample of 2, one "extra-spot" presumably gamma zein, from a transgenic exposure, while reporting only 2 spots in the non-GM sample from the other person. This is most likely experimental error and the IgE binding has no proven link to food allergy differences in this case, particularly inasmuch as gamma zein has not, in fact, been shown to be allergenic. Lipid transfer protein is the only proven important food allergen for maize and it varies markedly (see Goodman et al., 2008).

In particular, the conclusions in Section 4 of the paper are telling: no statistically significant differences are noted.

For a final bit of context, it is worth noting that there are in the scientific and medical literature no reported cases of fatal food allergic response to corn, globally. Zero. For soy, in the United States, there is an average of one fatal food allergy reaction per year; for peanuts, approximately fifty. And researchers are working to use biotechnology to remove from these foods the proteins that elicit the allergic reactions. This has already been done for soy, and is

well along in peanuts. In other words, far from being the source of food allergenicity hazards, biotechnology offers possible solutions available in no other way.

HANSEN: So that, yes. There's many studies. I can submit them to you. There've been review articles that have pointed out these problems and they're linked in my testimony. Look at the footnotes and you can link to the studies themselves.

As noted above, the handful of papers that Hansen repeatedly cites have, without exception, either been found to be fatally flawed, or as with Fonseca et al. above, they fail to support the claims made for them.

ASSEMBLY MEMBER SKOUFIS: Okay just one last question and to continue what Assemblyman Simanowitz said, now when I walk into a grocery store typically you know when I go shopping, there's an organic section and then there's the rest of the supermarket. In response to his question you said that's you know labeling will help affirmatively determine what the person was exposed to, should there be some kind of health problem. Take me through that process. You know a person goes to a DR. The Dr says you know what did you eat and we want to see you know how it affected the problem we have right now. You know short of someone keeping a journal about what they ate and keeping the labels or whatever it might be. You know, how does labeling help along that process?

HANSEN: Well it's the same way we do epidemiology now anyway. So for example say you're allergic to kiwi fruits… The Industry has brought this up. The first time you find that out, is say you're eating a fruit salad and you have this reaction, what the Doctor does is, you have to recall all the food you ate in the last 24 hours. You exclude those and then you bring them in one at a time, right? Now let's say somebody's taken the gene for kiwi fruit and they put it in a tomato and you eat a pizza and have an adverse reaction later. You can remember everything you ate. Once you bring each of those foods back into the diet, if you bring the tomato in and it's not the engineered one, you're not going to respond to it. So that way, if it's labeled, where you can possibly figure it out. Not always but at least you have a chance of doing that and that's how these food recalls happen. It's the same thing when there's an outbreak of some disease and they're trying to figure out, is it linked to tomatoes? Is it linked to peppers? That's epidemiology. You go and you ask people that have got sick what have you been eating.

The imaginary example provided does not support the argument in which it is used. Kiwis are known to be allergenic. Under existing FDA regulations covering bioengineered, and all foods, any food containing genes derived from kiwi fruit (or any other members of the family Actinidiaceae) would be required to carry a label so indicating.

ASSEMBLY MEMBER BUCHWALD: If a product is labeled organic, can a consumer automatically conclude that it's GMO free?

HANSEN: They can conclude that engineered materials are not supposed to knowingly be used in it. Could there be some contamination? Could there be some level of GE in organic? The answer to that is yes.

ASSEMBLY MEMBER BUCHWALD: Given that, do you think that the legislation before us should include a blanket exception for organically produced foods?

HANSEN: Well yes because GE cannot be used as part of organic. Just like there's an exception in here that says if a farmer doesn't knowingly use them. Say they buy seed that's certified as conventional soy beans or conventional corn. Somebody could test that and maybe there's one in a thousand, one in ten thousand trace contamination. Well that's not what the farmer intended or knew about. That's why that's exempted, so yes I do think there should be an organic exemption.

While food knowingly grown from biotech improved seeds cannot carry the "USDA Organic" label, such seeds can certainly be planted and grown with organic methods. Indeed, the concept is strongly favored by some organic growers.

ASSEMBLY MEMBER BUCHWALD: Should we have an exception for any product produced by a farmer, who doesn't knowingly produce or have genetically modified components?

HANSEN: That's already in there… ...what the difference is the organic, there's already legislation about what organic is and it very clearly says genetic engineering cannot be part of organic. That was clearly done, so there's already regulatory history for that. That's why they decided if we're going to do a legislation, that's already carved out for the organic portion. Now for a conventional farmer, if they're buying conventional seed and they don't knowingly use it, then that would put them functionally I guess in the same, well it isn't in the same category because with organic you're forbidden from using those engineered ones. A conventional farmer you're not. It's if you choose not to do it and you can show look I bought non-engineered seed. Then if they end up being contaminated, that's inadvertent and you're not responsible.

ASSEMBLY MEMBER BUCHWALD: And Dr. Hansen are there genetically modified foods that you consider safe?

HANSEN: Well I will put it this way. There have been none that I've seen that have gone through a full safety assessment, so I don't know. They could all be safe or they could not be. You don't know until you do the studies.

These claims are abundantly refuted by the conclusions of regulatory bodies in the United States and around the world. Every bioengineered food placed on the market in the United States has gone through an extensive safety assessment in accordance with best practices, as defined by the worldwide consensus of experts in the field. These same products have been subject to mandatory and substantially equivalent reviews in other countries as well, including Japan, Korea, Australia, New Zealand, the European Union, and others. As documented above, abundant studies have been done, including many by independent scientists with no connections to industry. The findings of all this research and the vast body of concrete experience accumulated as a result of the consumption by humans and animals to the tune of billions upon billions of tons over the past two decades lead to one clear

conclusion: crops and foods improved through biotechnology have been subjected to more scrutiny, in advance, in depth and detail, than any other foods in human history. They have an unblemished record of safety.

ASSEMBLY MEMBER BUCHWALD: And so building on that, you mentioned the New York Times article this past Sunday on the effects of a genetically modified orange resistant to the citrus greening disease bacterial infections. The article lays out a three step testing regime for this new type of orange. First the EPA conducts animal tests to assess the safety of the protein produced by the new gene. Second, that there's a test of the protein as it appears in the pollen of the transgenic orange blossoms and third, that the juice is tested to compare safety and nutritional content to conventional oranges and you've stated that the US does not require safety testing for genetically engineered plants?

HANSEN: I said the FDA doesn't. What you're talking about that case is that's EPA doing that because that engineered gene that they would put in there, they would consider that as a pesticide, as a sort of plant pest and it's under the EPA guidelines. The plant pest themselves, would have to be looked at, so they would look at the protein. Since that would be considered a pesticide. That would be the EPA looking at that. They would not look at for example unintended consequences. The fact that the genetic engineering could have turned on toxins or changed other characteristics. That's not under that purview and that's something that again globally there's been an agreement that that unintended effects should all be looked for. That's not what EPA does. They only would narrowly look for that as they said, that bacterial trade and if you read it, it wouldn't even be the one that was produced in the plant. They were going to let them produce it in bacteria or their feeding studies and so that's EPA testing. That's not FDA and FDA is the one that's responsible for the full food safety assessment. So they should be looking at the unintended effects as well and this would not do that.

ASSEMBLY MEMBER BUCHWALD: So in your written testimony which you submitted to the committee, where you write unlike in other developed countries, the US does not require genetically engineered foods to be proven safe before they can go onto the market despite significant safety concerns?

HANSEN: That's correct.

Mr. Hansen's assertion is abundantly contradicted by the scientific literature and a vast body of concrete experience. There are no safety concerns associated with any of the bioengineered foods/feeds on the market anywhere in the world any different than those associated with their conventional counterparts.

ASSEMBLY MEMBER BUCHWALD: You're saying there are times that genetically engineered foods are tested by the US government but they're not tested for safety? At least all the elements of safety that you believe [unintelligible] ?

HANSEN: Yes when you're talking about safety, if you want to get into detail the EPA does look for example at the BT crops. They have done safety assessments for the actual protein it was engineered in.

Now our criticism of that is, is though safety testing test have been done with the BT protein that is produced by an engineered bacteria. Not that is produced by the plant itself. That is the only thing that the EPA does. So if there've been safety assessments, they have been not for the food but just for that one component of it and that's not a complete safety assessment. Yes those parts have been done and we have criticized each of the BT assessments because they're not using the BT that occurs in the plant, they're using a bacterial composition.

HANSEN: The EPA is testing and then when they say they'll look at the various juice components, that's part of what the companies called substantial equivalence. They can look at a range of that but again, for that orange, there would be no requirement for the FDA for example to say we have looked at this and we think this is safe. What would happen is that company will get a letter just like the one I read you and there will be a sentence in there that will say that it is their understanding that whoever did that orange, has concluded that the orange and the products derived from it are not materially different. The FDA would not make a conclusion about the safety and that's the difference. We're asking for the FDA like they would for a food additive to evaluate something to see if it meets the legal criteria of reasonable certainty of no harm. That doesn't happen at this point. The discussion in the Sunday Times, that still would not happen. Little portions of that there might be people that look at the various differences in parts of the juice but that's not where my safety concern would be.

HANSEN: …again the problem would be the protein that they're testing for, is not the one that occurs in the plant. The one that occurs in the plant is actually different because it has sugar groups and all these other things on it. I would say that the science advisory panel to EPA has told them this over and over again that you should be using the protein that occurs in the plant. They do not do that. We have said that they should do that. Their own scientific advisory panel has said they should do that and they don't, so yes there some safety assessment from EPA but it is inadequate in my view.

ASSEMBLY MEMBER BUCHWALD: Isn't step two as laid on the article testing of the protein as it appears in the pollen of the transgenic of the blossom?

HANSEN: That is a good thing because that would actually get the pollen as it appears and yes looking at feeding that pollen to see whether it can disrupt pollinators or other things. That's eco-toxicology, that's wonderful and yes that should be done.

As a final comment, while proponents of labeling measures such as those supported here by Hansen most often claim they seek mandatory labels to enable consumer choice, or to address safety issues, it has been noted that the effects of such labeling mandates would advance the financial interests of the major funders of these labeling efforts. Indeed, the major drivers have been quite candid about their actual objectives, which in fact have nothing at all to do with consumer choice or safety but rather with driving the adoption of organic food.