Testimony of

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On

"A National Framework for the Review and Labeling of Biotechnology in Food"

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Introduction & Summary

Chairman Pitts, Ranking Member Green, and members of the Subcommittee, thank you for inviting me to share the views of the Information Technology and Innovation Foundation (ITIF) on the safety of and appropriate labeling for crops and foods improved through biotechnology.

The Information Technology and Innovation Foundation (ITIF) is a non-partisan research and educational institute—a think tank—whose mission is to formulate and promote public policies to advance technological innovation and productivity internationally, in Washington, and in the states. Recognizing the vital role of technology in ensuring prosperity, ITIF focuses on innovation issues. Because of its importance in enabling agricultural innovation, we have long been involved in the conversations about agricultural biotechnology and how best to ensure its widely shared benefits to humans and the environment are not unduly burdened by ill-considered policies, especially those based on fear and misunderstanding. I very much appreciate the opportunity to comment on these issues here today.

My comments come in the context of HR 1599. While I agree strongly with the obvious and logical importance of pre-empting State level efforts to require labels for food containing "GMOs," I concur with former FDA Commissioner Dr. Margaret Hamburg, who stated last summer that FDA already has clear and sufficient authority over food labels, and that FDA's authority pre-empts State level action.[1] As you have heard from other witnesses, the costs and negative impacts of a fifty state patchwork of inconsistent and incoherent standards would be significant. In view of the scientific consensus on, and unblemished safety record of bioengineered foods, together with clear Congressional supremacy, there is no conceivable justification for a state by state approach, much less for any mandatory labeling initiatives other than those that have already been in place at the federal level for decades.

It is worthwhile to focus on the reason for HR 1599. It has been put forward as a means of addressing campaigns to create exactly the sort of 50 state patchworks for which there is simply no justification. Legal mandates already require that consumers have all information relevant to health, safety, and nutrition, on federally approved labels. Numerous measures now in place (some already for years) provide consumers with abundant opportunities to choose to avoid foods derived from crops improved through biotechnology, should they wish to do so despite the abundant data and experience confirming their safety and environmental benefits. Yet a small group of professional campaigners has spent no small amount of money and effort to create the illusion of a demand for federal action that was, in fact, taken more than two decades ago. This entire issue, then, is merely a subterfuge through which ideologically-based anti-technology special interests are seeking to roll back and ultimately completely remove from the market GMO-based products.

On the issue of safety, though some will claim otherwise, the fact is that hundreds of billions of meals have been eaten by more than a hundred billion livestock animals, and billions of humans, in the two decades these foods have been on the market. There has been not a single solitary case of a negative health consequence as a result. It is a record of which the organic industry, for one, should be envious. The global scientific consensus on the safety of these foods and crops is remarkable in its breadth and depth.

The wisdom of FDA's 1992 policy statement is therefore clear. Just as scientific and professional bodies around the world have done, the FDA found that there is nothing about the processes of

bioengineering that necessarily changes the resulting foods in any way related to health, safety or nutrition. If such a change were to result, as in the case of cooking oils modified to be more heart healthy, or soybeans with improved nutrition thanks to the addition of a gene encoding protein from a tree nut, the resulting foods would already be required, under existing FDA policy, to carry a label that would inform consumers of such changes.

Some have claimed that consumers have a "right to know" if their food has been "genetically modified." Those making such claims overlook the fact that "genetic modification" is a process, not a thing. And as a geneticist, I can state categorically that every food any human has ever eaten has been "genetically modified" in the literal meaning of the term. Proponents of mandatory labels so misunderstand the facts as we find them in nature that they define "GM" as a process resulting in genetic changes in a manner not found in nature. This ignores that the processes used by genetic engineers are ones we learned about by finding them operating everywhere in nature. In fact, no process is more natural than genetic modification, and the scientists who use it to improve seeds do so using systems they bring from nature into the lab for the purpose.

Current FDA policy requires that any food that has been changed, by any means, so that its composition is different in any way related to health, safety, or nutrition, must inform consumers of such changes on the label. Furthermore, this must be done in a manner that is safe, informative, and not misleading. In short, the things proponents of mandatory labels claim they want, they already have. But of course, proponents of mandatory labeling do not want labeling to inform consumers, they want labeling to scare consumers and force food companies into not buying food inputs with "GMO" ingredients.

Authority to Set Labeling Standards – Congress or the States?

Article I, Section 8, Clause 3 of the Constitution, the "interstate commerce clause," clearly locates the authority "to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes" among the powers reserved to Congress. Congress in turn has delegated to FDA, through the Federal Food Drug & Cosmetic Act[2], authority over food labels. And FDA has laid out national policy in this regard in a 1992 Guidance Document.[3] In publishing this guidance, FDA has followed the strong international consensus.

As mentioned above, existing FDA regulations already require that any novel ingredient that may affect the health, safety, or nutritional value of a food must be identified on the label. Existing federal law requires all food placed on the market to be safe, with criminal penalties for violators. Consumers have a right to labels that are accurate, informative, and not misleading.

Some claim that the processes used to produce bioengineered foods are fundamentally different from those used to develop other foods, and that insufficient studies have been done to allow us to be confident of their safety. Such allegations are false. Plant breeders and credible scientists around the world 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.[4]The U.S. National Academy of Sciences explicitly rejected this claim in its very first publication in this area[5] 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[6]. The government of Australia has done likewise[7] and the overwhelming majority of scientists around the world concur in this assessment.[8]

Indeed, the advent of modern genomics has shown us that genes are shared and transferred widely not only among different species, but between genera, families, and even phyla and kingdoms. Recent discoveries[9] have confirmed that gene exchange was the essential element in the survival of ferns when the explosive radiation of flowering plants radically changed their environment. This natural gene transfer is just like that used by modern genetic engineers to create plants improved through biotechnology. These natural processes of gene exchange are so widespread among plants, animals, and microbes on planet Earth that the single most common gene in humans is one that came from a virus[10]; as did half[11] of the other genes in our genomes; and humans share[12] 98% of our genes with chimpanzees, 92% with mice, 44% with fruit flies, 26% with yeast, and 18% with dandelions. Those who claim crops improved through biotechnology are "unnatural" could not be more profoundly refuted than by what we find throughout nature.

Global Consensus on the Safety of Foods Derived From Crops Improved Through Biotechnology

Some claim there are unresolved safety concerns about GIFS, and that they have been insufficiently studied. These claims are false, robustly contradicted by the scientific literature[13], worldwide scientific opinion, and vast experience.[14] Some have claimed that there is a dearth of independent research evaluating the safety of crops and foods produced through biotechnology, and that companies hide behind intellectual property claims to prevent such research from being done. These claims are false. The American Seed Trade Association has a policy[15] in place to ensure research access to transgenic seeds, and Monsanto has made public a similar commitment.[16] The academic scientists who made the 2009 complaint cited above, in fact, had the access they sought at the time they made the unfounded complaint.

In fact, there has been an abundance of independent research over the years,[17] including 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…'

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."[18]

> "…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."[19]

> "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."[20]

The Union of the German Academies of Science and Humanities found: "…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."[21]

The Chief Scientific Advisor to the European Union stated, "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."[22]

"GMO products have been tested to a particularly high extent and are subjected to rigid legislation control."[23]

"Food from GM Maize is more healthy than from conventionally grown maize… samples with the highest fumonisin concentrations are found in products labeled 'organic.' "[24]

"…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."[25]

"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."[26]

As for claims 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 harbors any recognizable health risk."[27]

The most recent scientific publication[28] in this crowded catalogue examined the effects on livestock of eating feed derived through biotech improved crops over the course of 29 years through more

than a trillion meals. This unprecedented observational study not only failed to find any negative impacts, it found that over this period the average health of livestock animals improved.

Claims of the Anti-GMO Advocacy Groups

Despite the overwhelming consensus documented above, professional anti-technology campaigners claim that this consensus does not exist, and that its absence is demonstrated by "a petition signed by over three hundred scientists." This false assertion presents no new arguments or data, and ignores the staggering mass of studies already cited demonstrating the safety of these foods, and their unblemished safety record. Instead, it recycles the usual stable of discredited claims such as those of Séralini et al.[29] 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 observer[30] has dismissed them with these words:

> "A group of [300] "scientists have signed a letter saying "GMO is bad…" They did so in response to a roundup of more than 2,000 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."
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> "Scientific consensus is not done by opinion poll, nor is it done by petition…. The scientific consensus is a consensus of data, 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."
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> 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…
>
> "The World Health Organization (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'."
>
> "The Agricultural Biotechnology Council (ABC) of Australia said the ENSSER's statement "flies in the face of a consensus of an overwhelming majority of scientists."
>
> "Every legitimate scientific organization 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.
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> "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.

Ignoring all this, professional anti-biotechnology campaigners persist in their claims that there are studies raising legitimate questions about the safety of GIFs. One frequently cited example is that of a long term feeding study in rats, conducted by a well-known organic advocate and biotech opponent from France, who dissembled about his financial conflicts of interest that lay behind his claims. Biotech opponents claim this study has been wrongly criticized, but the facts repudiate this claim. The alleged "attacks in the media" aimed at the Séralini "study" were the direct consequence of its remarkably poor design, execution, and analysis[31] and the unprecedented media manipulations[32] imposed on journalists 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[33] and journalists.[34] That is how peer review[35] 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.

One consistent opponent of agricultural biotechnology [36] has claimed that "*the French Food Safety Agency and the European Food Safety Authority have functionally agreed with Doctor Séralini."* This claim is flatly contradicted by the historical record. Regulatory bodies in Europe and around the world uniformly rejected the study, and have made strongly critical statements.

The European Food Safety Authority: "EFSA is presently unable to regard the authors' conclusions as scientifically sound."[37] Six French National Academies of Science (Agriculture, Medicine, Pharmacology, Sciences, Technology, and Veterinary Medicine) condemned[38] 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 authorized 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[39] by the French Higher Biotechnologies Council (HCB) and the National Agency for Food Safety (ANSES).

The German Federal Institute for Risk Assessment: (BfR): "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."[40]

The Australia New Zealand Food Safety Authority stated,[41] "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's Health agency 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."[42]

Indeed, the condemnation of the Séralini 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."[43] One blogger distilled the consensus, and coined the "Séralini Rule": "If you favorably cite the 2012 Séralini rats fed on Roundup ready maize study, you just lost the argument."[44]

In the end, the evidence of the study's inadequacies was so overwhelming that the journal in which it was published retracted[45] it, providing this explanation[46] from the editor and eliciting[47] much commentary[48] in the blogosphere.[49] Séralini apologists have made numerous false and misleading claims about the retraction, but these have failed to persuade.[50]

It must be noted that in citing the robustly discredited Séralini. study opponents illustrate a pattern they have followed throughout their public representations. Repeatedly they cite one or another from a small handful of studies published by well-known campaigners against biotechnology. In so doing, they ignore the devastating criticisms they have received from the scientific community (peer review[51]) as well as the vast body of accepted scientific literature contradicting their unsustainable claims. This pattern of advocacy is deemed to be scientific misconduct under widely accepted standards. [52]

Some have claimed that crops improved through biotechnology have resulted in an increase in the use of pesticides. This claim is, at least, mischievous, if not false, and depends on a number of intellectual gymnastics:

- It wrongly conflates "herbicides" with "pesticides" in a way that is flatly misleading. Pesticides are commonly understood to kill pests, usually insects. Herbicides are used to control weeds, which are certainly pestiferous, but agriculturalists use the different words for very good reasons;
- The argument is based on the misleading measurement "pounds on the ground" when that has long since been supplanted in the weed control literature by the "Environmental Impact Quotient" developed at Cornell University. The EIQ gives a vastly more accurate and useful way to evaluate comparative environmental impacts;

- The argument measures absolute application rates, instead of the far more logical rates per unit yield, which actually show a decline[53] in herbicide usage;
- Such claims ignore the devastating critiques that have been leveled specifically at his claims in at least 17 peer reviewed papers[54] in the literature and several accessible blogposts;[55]
- Such claims are, in fact, directly contradicted by USDA's interpretations[56] of their own data.

In addition to these spurious claims that seem designed deliberately to mislead consumers about the environmental safety of foods derived from crops improved through biotechnology, we are routinely bombarded with a host of claims about alleged dangers to humans from their consumption. In an arena marked by the incredible, it is hard to find claims that are farther "out there," divorced from reality, than those that have been advanced by Dr. Stephanie Seneff, an engineering PhD who seems to have some difficulty identifying any evils that cannot be laid at the feet of glyphosate.

The facts tell quite a different story. One can hardly do better than to consult a summary of the data on the safety of glyphosate compiled by independent scientists at BioFortified last year,[57] with a useful primer also available.[58] Bottom line – glyphosate is less toxic than table salt, baking soda, chocolate, or caffeine. Yet some would have us believe it is responsible for nearly every ailment imaginable[59], and these claims find a ready echo chamber in a credulous and scientifically ill-trained press.[60]

The claims made by Dr. Seneff are so outlandish they cannot be taken seriously. Let me draw your attention to a few relevant points. The paper in which the claims were made was published in an obscure, pay-for-play journal that is not even indexed in the standard catalogue of biomedical journals, PubMed[61], and not devoted to the topic of the paper. Moreover, no credible mechanism is presented which could conceivably explain the wide range of disparate claims of harm nor is the argument based on any demonstration of causality, but on dubious inferences of correlation.

At the end of the day, it is important to remember that unlike conventional or organic foods, bioengineered foods are routinely screened in the United States and other industrial nations (per regulations rooted in the OECD guidelines) to ensure they have 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.[62] 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.

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.[63]

Motivations of the Anti-GMO Advocacy Groups

If protecting human health or the environment is not the objective for these anti-technology opponents, what is? To be clear the real objective behind the campaign for legislation to mandate

"GMO" labels being advanced in a number of legislatures is to falsely stigmatize 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 as the following quotes show:[64]

> Andrew Kimbrell, Executive Director of the "Center for Food Safety, has stated "We are going to force them to label this food. If we have it labeled, then we can organize people not to buy it."
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> Joseph Mercola, who makes a living selling unregulated, unlabeled supplements at mercola.com, has stated "Personally, I believe GM foods must be banned entirely, but labelling is the most efficient way to achieve this. Since 85% of the public will refuse to buy foods they know to be genetically modified, this will effectively eliminate them from the market just the way it was done in Europe."
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> Jeffrey Smith, self-publisher of some of the most imaginative[65] anti-biotechnology claims, has said "By avoiding GMOs you contribute to the tipping point of consumer rejection, forcing them out of our food supply."
>
> Professional campaigner Vandana Shiva said "With labeling it (GMOs) will become 0%... for you the label issues is vital, if you get labeling then GMOs are dead end. "
>
> And the Director of the Organic Consumers Association, Ronnie Cummins, said "The burning question for us all then becomes how -- and how quickly -- we can move healthy, organic products from a 4.2% market niche, to the dominant force in American food and farming? The first step is to change our labeling laws."

And most recently "mandatory labeling and bans, or GMO-free zones, should be seen as complementary, rather than contradictory."[66]

It takes very little digging to uncover the motivations behind this organized push for mandatory labeling: it is a fear-based marketing campaign[67] motivated by an attempt to expand the market share for organic foods. And this is because these advocates simply distrust technological innovation *per se*, preferring Americans, and the rest of the world, to live in an idyllic, simpler world they believe is closer to a "nature" that meant life spans were half or less what they are today, child mortality at 80 percent or more, and malnutrition and starvation widespread. The reality is that if these neo-Luddites are able to impose their vision of a world on us – a world without GMOs – it will be a world with higher food prices. Perhaps labeling advocates can afford to pay higher prices for organic foods at upscale stores like Whole Foods – which is and should be their right – but using state legislatures to force all Americans down this path (e.g., to spend much more than necessary for safe and wholesome food) is elitist at its core.

Consumers have a right not only to not be deceived and misled. They also have a right not to be forced to pay more for food so they have more money for health care, education and other needs. Compulsory labeling of "GMOs" would deprive them of these rights.

Thank you again, Chairman Pitts, Ranking Member Green, and members of the Subcommittee for giving me the opportunity to appear before you today. I will be happy to answer any questions.

Endnotes

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