Franken-Food or Scare Tactics? The Science, Law and Policy of Genetically Modified Foods

Excerpts from an Expert Panel Discussion

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Introduction

On September 10, 2013, the NYSBA Health Law Section's Committee on Medical Research and Biotechnology[1] held a public symposium to explore the scientific, legal and public health issues involved with genetically modified organisms (GMOs). The goal of the symposium was to start a public dialogue in light of the significant legislative activity and proposals surrounding GMOs particularly in the states of California and New York.

Genetically modified foods have been marketed and consumed for many years in the United States. Farmers have been selecting for particular strains of plants or animals for thousands of years through selective breeding, a technique that crosses plants and animals from related species. Another method of producing crops with useful traits is genetic engineering, the product of which we call GMOs. These are plants or animals that have deoxyribonucleic acid (DNA) from other organisms (such as bacteria or viruses) intentionally introduced into that crop or animal using recombinant DNA laboratory techniques. The combining of genes from those different species doesn't usually occur in nature or through traditional breeding methods. In the United States, crops that have been engineered includes soybeans, cotton, canola, corn, sugar beets, Hawaiian papaya, alfalfa, and squash (zucchini and yellow). Food manufacturers estimate that over 70% of the food products consumed in the U.S. today contain at least one ingredient made from a GMO crop. In addition, GMOs (e.g., bacteria, fungi) are widely used by food manufacturers as processing agents to produce specific ingredients. Common ingredients derived from GMOs include corn oil, soybean oil, cottonseed oil, high-fructose corn syrup, table sugar, and soy lecithin. With the increased prevalence of genetically modified (GM) ingredients in food, there is much debate regarding the safety of those ingredients on human health and the impact of GM crops on the environment. For consumers, it can be difficult to determine which ingredients are made from engineered crops as new GMO crops may be entering the market soon (such as engineered apples and potatoes). There have been recent calls to strengthen legislation and regulations regarding GMOs from measures to ban the growing of GM crops to require mandatory labeling of foods using ingredients made from GMOs.

The symposium addressed the following topics:

- GMO safety, environmental impact, and impact on food production;
- Perspectives on the benefits and risks of GMOs;
- The current state and federal regulatory frameworks regarding labeling and other legal issues that apply to GMOs;
- The European Union's approach to GMOs.

The program panelists and moderator for the evening included:

- **David O. Carpenter, M.D.**, (Panelist) Director, Institute for Health and the Environment, University at Albany School of Public Health. Previously, he was the Director of the Wadsworth Laboratories for the New York State Department of Health. Dr. Carpenter has an active research program focusing on the study of human diseases in relation to exposure to environmental contaminants.
- **Dr. Cathleen Enright, Ph.D.**, (Panelist) Executive Vice President of the Food and Agriculture Section in The Biotechnology Industry Organization (BIO), a 1,100+ member organization in the United States and abroad.
- **Mr. Gregory Jaffe, J.D.**, (Panelist) Biotechnology Project Director at the Center for Science in the Public Interest (CSPI), a nonprofit consumer organization located in Washington, D.C. working on food and nutrition issues. He was previously at

the Department of Justice and EPA as an environmental civil litigator. CSPI originally petitioned the FDA in 1995 to mandate the labeling of trans-fat, which is now in place.

- **Ms. Patty Lovera**, (Panelist) Assistant Director of Food & Water Watch, a consumer advocacy organization focusing on food policies ranging from the Farm Bill to food labeling and safety standards as well as water issues.
- **Ms. Beth Roxland, J.D.**, M. Bioethics, (Moderator) Adjunct Professor, New York University School of Law and Associate of the Division of Medical Ethics, New York University Medical School, who provided an overview of the legal issues. She was previously Executive Director of the New York State Task Force on Life and the Law and Special Advisor to the Commissioner on Stem Cell Research Ethics.

Following is an edited transcript from the meeting.

Ms. Roxland: With all the concerns surrounding GMOs, how are they currently regulated in this country?

Mr. Jaffe: The federal regulation of these crops is a little convoluted. Depending on the crop and the trait, it can fall under the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and/or the U.S. Department of Agriculture (USDA).

Ms. Lovera: While the federal government has oversight over what is or is not included in an ingredient list, there has been tremendous lobbying activity in the area of GMOs. So, it has been the FDA's policy for over 15 years not to include GMO in those labels. Today, there is an increasing groundswell of public interest for lots of reasons which build on the predecessor controversy surrounding the use of recombinant bovine growth hormone (rBGH), an artificial growth hormone given to dairy cows to promote more milk production. In both instances, these products are controversial in terms of health questions, generating much conversation about safety and whether they should be approved. Like GMOs, rBGH usage was approved with no mandatory labeling and no disclosure that it was used on the cows. So while we would prefer that the federal government list genetically engineered (GE) ingredients on a product label, we don't think that the feds will lead on this right now. As a result, we're talking to state legislatures. But the question is where will this information be placed if not on the label?

Dr. Carpenter: A bigger issue, in my judgment, that is the government (federal or state) doesn't regulate a lot of things that are very much more dangerous than GMOs, in particular the presence of known carcinogens in our food supply. Certain foods may contain high doses of chlorinated pesticides like DDT, or dioxins or PCBs. The FDA standards for allowing these foods to be sold are very, very loose and nobody is informing the consumer about that when they buy fish from the Great Lakes, for example. One can talk about the plasticizers in all of our plastic products that are endocrine disrupters that feminize little boys and increase the risk of breast cancer. This may be a debate, makes great press, but it's not really regulated. So, I think one has to put the GMOs in the context of other things that our government does not regulate.

Ms. Roxland: Who else in the federal government is looking at this?

Mr. Jaffe: The USDA, under the Plant Protection Act (PPA), regulates any crop that could be a plant pest.[2] If a developer or a researcher wants to do a field trial of GMO crops, they will need a permit from USDA. At the end of their field trials, the developer must prove to the USDA's satisfaction that there are no plant pest characteristics with that crop so it can obtain "nonregulated" status and be freely planted by farmers. The EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act. If the engineered crop produces a biological pesticide (such as a gene from Bacillus Thuringiensis (Bt) that produces a biological toxin) the engineered crop needs to be registered under FIFRA, which requires both the performance of an environmental risk assessment and the setting of a food safety tolerance for any potential pesticide residues.

Dr. Enright: Interestingly, none of the products of the other breeding technologies (i.e., selective breeding, hybridization, mutagenesis, somaclonal variation) goes before the FDA because genetic engineering was considered an extension of traditional breeding. Because of a concern about public acceptance, companies voluntarily submit safety information to the FDA for review.

Ms. Roxland: Is it correct that the FDA requires a voluntary submission on the part of the developer when reviewing the food safety of a GE plant or crop entering our food supply? If so, how is it different from what is going on in other countries?

Mr. Jaffe: Generally the burden of proof as to whether a product, a drug or pesticide, for example, is safe, is on the developer of that product. Once the developer overcomes that burden, the product is approved. Though the FDA oversees the safety of our food supply, including the safety of foods produced from plants, there's no formal approval process for GMOs. Under the Food, Drug and Cosmetic Act, only food additives require mandatory premarket approval from FDA. The FDA made a scientific and factual determination in 1992 that introducing new DNA and proteins generally does not make an existing crop a food additive. It is instead generally recognized as safe (GRAS). Under these circumstances, companies developing GMO crops can self-affirm GRAS. GMO developers can voluntarily provide the FDA with safety data through a voluntary consultation process. The FDA

reviews that data package to make sure that the developer hasn't missed anything, and asks questions as they see fit. Ultimately, the responsibility for safety rests on the developer. So far, this voluntary process has been followed for all commercialized GMO crops. The European Union, on the other hand, has developed a more rigorous mandatory regulatory process. So, if we want to sell corn and soybeans to Europe or Japan, we must satisfy their regulatory requirements.

Dr. Enright: Even though the system at the FDA is voluntary, the companies don't pick and choose what data is required for submission. As a result, there is a mandatory system similar to our voluntary system. One of the questions I am asked is: "Well, what if there's data that's not favorable to the product?" The information that our companies provide to USDA, EPA and FDA is largely the same information that they've presented to the European scientific body, the European Food Safety Association (EPSA).

Mr. Jaffe: In the case of GMOs, the international standards are set forth by the Codex Alimentarius, and the required data submission in Canada, Europe and Japan mirror the data that's generally submitted by the companies to FDA here in the U.S. The difference is that FDA does not tell the American public its opinion on the safety of the GMO crop. My criticism with this system is there needs to be a change in the burden of proof. Under the current system, the law allows the FDA to go after companies that market "adulterated" food. It's the FDA's burden to show that it's adulterated, as opposed to the developer showing it's safe before it enters the food supply. In other countries, before it even gets on the market, they have to get approval from the regulatory body. To me, that's a difference in burden of proof even if the data that's submitted or the actual safety is not any different.

Ms. Lovera: The European Union looks at this as a novel food technology. Our regulatory system is not equipped to deal with what is a new technology. We have a patchwork that doesn't really step up and give the public an independent objective look at it. This comes up not just for transgenic animals or other biotech but also in many food technologies. Accountability is currently an issue as well related to who is supplying this data, whether anyone else is able to look at it, can it be replicated and whether there is any non-industry funded work. This is not the FDA's job under the existing regulatory scheme. Our government does not provide grants to study the hazards of GMOs so we are dependent on industry-funded reports. That's not to say it's all wrong, but there should be a counterbalance of independent investigation. We think that it's time to have that conversation about an adequate way to regulate this. The Pew Charitable Trust is doing a big project about how [the current system is] really not adequate to protect the public health on anything you're adding to food, let alone something that we think brings in lots new issues like genetic engineering. The last thing that I'll say is we haven't yet talked about genetically engineered animals. There has been one in the pipeline: genetically engineered salmon. These animals are being regulated as a veterinary drug, which is incredibly not a transparent process for the public. What we have now, after three years of very public debate on this, is our summary charts and that which the FDA made public. We don't have access to the data though. Much like a drug approval, that information will not be public until it has been approved.

Ms. Roxland: The FDA issued guidelines on labeling in 1992 and later in 2001 issued for notice and comment a draft set of guidelines on voluntary labeling of GMO products.[3] To date, the FDA never finalized the guidance and there are now calls to finalize that guidance.

Mr. Jaffe: FDA has draft guidance on labeling of foods made from GMO crops. FDA said that because there is no difference between the safety of a genetically modified crop and a non-genetically modified crop, there is no mandatory requirement to label GMOs. The guidance states GMO ingredients need to be labeled if there is a nutritional change or different functional characteristics for the ingredient produced by the GMO (e.g., high oleic soybean oil instead of soybean oil). I think that one of the biggest reasons behind the whole labeling debate is that many members of the public are not convinced that GMOs are safe. In my opinion, the most important public policy to address that concern would be to have a mandatory FDA premarket approval for GMOs prior to allowing them to enter our food supply. Ensuring safety before marketing the crop is much better than putting GMOs out there, identifying them with a label, and letting the public choose based on whatever they may or may not know about those foods. We'd make our regulatory system similar to Canada's, Japan's and other countries around the world where our consumers would hear from FDA about whether the GMO is safe, see the relevant data in a transparent process with public participation, and understand FDA's analysis and reasoning behind their determination of safety. This should be the number one legislative priority. Labeling should not be a surrogate for safety. The other point I'd like to make concerning labeling is this. There are over 65 countries that have mandatory labeling regulations but those national requirements are not uniform. For example, China exempts soybean oil totally from GMO labeling while Japan requires a GMO label only if one of the first three ingredients came from a GMO crop. So, any labeling should be based on science and facts and must be both accurate and not misleading.

Ms. Roxland: Based on our discussion, it seems that the federal government won't mandate labeling based on a "right to know" premise, but only perhaps if there are safety concerns or nutrients or allergens. What can citizens focus on if they want their state to pass a labeling law?

Ms. Lovera: This issue continues to evolve. We have changed the laws on labeling because debate leads to that change. Why? Because what consumers need to know to make an informed decision about what they are buying is evolving. We didn't always get ingredient labels or nutrition facts. We have country of origin labeling on foods because the public said that they wanted it. There are a lot of conversations about whose job it is to fix this. We think the federal government has failed on this. People have been beating their heads against the wall at the FDA for a long time trying to get them to listen to what most people want to know. This year, there were bills introduced in approximately 26 states. In the public health arena we're missing an opportunity to see what happens to people who eat GMOs and trace it back by not affirmatively including GMOs in labels. We know where GMOs are not found because certain food certifications, such as "certified organic" and other third party certifications, don't allow it.

Ms. Roxland: New York State actually has proposed a bill which is similar to the California initiative. Under the proposed bill, a GMO product would be misbranded/mislabeled if it did not carry a "genetically engineered" or "genetically modified" label on the front of the package or above/below the ingredients. This GE label would not be specific to the actual ingredients that were modified. The GE label would not be specific to the actual ingredients that were modified, such that a consumer would not necessarily know which component of their package was genetically engineered. There are also multiple exemptions listed in the bills. The issue here is whether or not these terms are sufficiently educational. Would it be more helpful to provide GE information elsewhere (such as on a website)? Do these terms belong on a label to begin with?

Ms. Lovera: With some slight variations, all these bills talk about labels that say either "Contains genetically engineered ingredients," or "Made with genetic engineering." They aren't warnings. They're statements of fact. Yet, despite their outward statements of support, there has been active opposition from trade associations like BIO and biotech companies in every state capital trying to stop these bills which would require these types of food labels. As an example, Pennsylvania's Department of Agriculture had proposed a rule making it illegal for dairy producers to state they were not using GE. A few months later, it popped up in another state and then by January 2013, it popped up in state legislatures all over the place. Suddenly we were in ten states trying to maintain the right for dairy producers to say that they weren't using this technology with the asterisks. That's already been established by the FDA that people were going to put that caveat on there, so it's a little hard for us to reconcile that with statements about how interested this industry is in having us know when they're actively fighting what we think are common sense disclosures that people have been consistently demanding based on polling over the years. This seems very basic to people that they should get to know what we think is a basic difference. It's not just over health concerns. We haven't really talked about the rest of the real social and economic impacts of this technology. Consumers are waking up to this. They want to vote on this but they need information to do that.

Dr. Enright: The biotech industry supports a consumer's right to know. We're very proud of the products we make. We have full confidence in their safety. The foods grown from those crops grown from our seeds are the most tested agricultural product in the history of food manufacturing and agriculture. We understand that calls for legislation around this topic won't be going away. But we also understand that it's not necessarily just based on a right to know but also a desire to move away from biotechnology, our technology and our seeds. Because we believe in the technology, we believe in the seeds and stand by the safety of the food made from it. As such, we cannot support efforts to try to, in some way, use a label to convey to consumers that this food is less good, less nutritious, less safe, or has a health concern associated with it. The science doesn't support it.

Mr. Jaffe: One of the principles that FDA ensures for all labeling is that it must be "accurate and not misleading." For labeling required by a state or the federal government, I think that's a really good principle. I think you have to look at the details of each state GMO labeling bill and figure out whether or not the information the consumer is going to get from these labels is accurate and not misleading. For example, do you need to use words such as "derived from genetically engineered corn" instead of "made with genetically modified organisms" to make the label accurate? Is labeling appropriate if there is no physical—or biological—difference between the GMO ingredients and its non-GMO equivalent, such as with high fructose corn syrup? The same could be said for sugar made from GMO sugar beets, which doesn't contain any DNA or protein. While those highly processed ingredients might require a label under a state labeling law, it would be misleading because the products are identical. On the other hand, requiring a label on the engineered sweet corn you are consuming would at least be factually accurate because each corn kernel has both the introduced new DNA and the protein made from that DNA. So one of the things to think about in all these labeling debates is not just whether it's mandatory or voluntary, but what will be labeled. Is that going to be accurate or misleading to the consumer, and what useful information will the consumer receive? The New York law prohibits actually putting which ingredient is genetically engineered in the ingredient list, which in my opinion might be a more factually accurate way to label. If you have a salad dressing and it has a little soybean oil in it, it would be more accurate to write in the ingredient list "genetic engineered

soybean oil" than to say on the front of the package that the salad dressing is "genetically engineered" (assuming of course that oil with no DNA or protein is required to be labeled at all). That soybean oil might be ingredient number 20 in terms of its percentage in the salad dressing. The N.Y. bill would require "genetically modified" somewhere on the package but that could be misleading because the engineered ingredients are a really small component of that food. I think one needs to think about these things.

Afternote: Where Does that Leave the NY Consumer?

Proposed 2015 Bills: S485-2015 and A617-2015

Democratic Assemblywoman Linda Rosenthal of Manhattan, and her co-sponsor, Republican Sen. Ken LaValle of Suffolk, drafted a bill in 2013 (re-introduced in 2014 and 2015) providing for the labeling of seeds, food or food products that contain a genetically engineered material or that are produced with a genetically engineered material.

The labeling requirement can be met in a variety of ways. While the manufacturer must label the food, in a clear and conspicuous manner on the package of such food, it can choose to use the words "produced with genetic engineering" or any other derivative of those words, or the initials "ge," "gm," "gmo," or derivative of those phrases.

The bill also anticipates some of the most difficult questions about labeling. For example, for livestock, it exempts:

> Food consisting entirely of, or derived entirely from, an animal that has not itself been produced by genetic engineering, regardless of whether the animal has been fed with any food produced with genetic engineering or treated with any drug or vaccine that has been produced with genetic engineering.[4]

And for processed foods, it exempts from labeling products that include genetically engineered materials as long as the genetically engineered materials do not account for more than 9/10ths of 1% of the total weight of the processed food.

The bill does not require restaurants or other food retailers to label their menu items, nor does it require individual ingredients to be labeled as GM on a product label.

Current status

The bill was, in a surprising development, voted down in the Consumer Protection Committee at the very end of the 2013 session, resulting in allegations that lobbyists for Monsanto and other manufacturers had succeeded in shifting members' votes.

Reintroduced for the 2015 session, the NY GMO Labeling bill (A.617) was successfully voted out of the Assembly Consumer Affairs and Protection Committee on March 3, 2015 in a 9 to 6 vote. As of this writing, it is under review by the Assembly Codes Committee.[5]

Passage of a labeling law in Vermont

Notably, Vermont passed a labeling law, effective July 1, 2016. It is the first state to do so. It is currently being sued by the industry, which seeks to have the law invalidated.

Endnotes

1. The NYSBA Health Law Section, Committee on Public Health, Health Law Committee of the New York City Bar Association, and the NYSBA Food, Drug and Cosmetic Law Section also participated in sponsoring this symposium.
2. "Pursuant to that grant of authority [the PPA], the Animal and Plant Health Inspection Service (APHIS) promulgated regulations that presume genetically engineered plants to be "plant pests"—and thus "regulated articles" under the PPA—until APHIS determines otherwise. However, any person may petition APHIS for a determination that a regulated article does not present a plant pest risk and therefore should not be subject to the applicable regulations. APHIS may grant such a petition in whole or in part." Monsanto Co. v. Geertson Seed Farms, 570 F.3d 1130 (2010).
3. Food Drug Administration (2001) DRAFT Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering. (FDA Maryland). Last accessed Feb. 2, 2015 at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm.
4. S485-2015 and A617-2015 §15(D)(I). Last accessed Feb. 4, 2015 at open.nysenate.gov/legislation/bill/A617-2015.
5. For up to date status of the bill, see: http://assembly.state.ny.us/leg/?default_fld=&bn=A00617&term=&Summary=Y&Actions=Y.