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GM Oh! Is it Right to Know?

What's in your diet? Today, some 70% of processed foods sold in the United States are said contain to genetically modified organisms, commonly referred to as GMO's (Editors). If you drink soda, eat chips, cereals, crackers or cookies, a portion of your diet is likely to contain genetically modified organisms. The FDA defines genetic engineering, or GE, as "the name for certain methods that scientists use to introduce new traits or characteristics to an organism" ("Questions"). Currently, the FDA does not require that GE producers label goods containing GMOs ("Questions"). Consequently, states are now looking to adopt their own laws requiring that genetically engineered food be labeled. One such proposal is the language of a California's ballot initiative, Proposition 37. Opponents of Prop. 37 are in favor of GMO technology and believe that the health and safety questions of genetically engineered foods have been conclusively settled by science. As such, they feel that mandatory labeling laws are unsupported by the data or the law. Supporters, however, say that consumers have a right to know if the food they buy contains genetically engineered food because they believe that GE crops have not yet been proven safe, and that GE producers should be better regulated to provide the transparency necessary for consumers to make informed decisions.

Those who oppose labeling generally support the technology of genetic engineering, regarding it as simply the latest scientific innovation of agriculture. Viewed in this context, labeling makes little sense, because it's just another method of improving food production, only marginally different from previous methods. Writing in opposition to Prop. 37, the editors of

Scientific American magazine compare genetic engineering with the ancient agricultural practice of selective breeding, noting that farmers have been altering the DNA of crops "since the dawn of agriculture" (Editors). Corn, for instance, is notable example of a food that was developed by humans long before plants were being genetically engineered (Editors). More recently, scientists have been learning how to "insert a gene here or tweak a gene there" in order to "[help] crops tolerate drought and resist herbicide" (Editors). That this method, or technique, of obtaining desired traits in a plant is different from older, traditional methods is irrelevant. Advances in science allow society to move forward, and biotechnology is no exception. As advances in science are made, technology will improve and further innovations will lead to even better techniques. New and innovative means of producing better products is not a reason to start making radical changes to the food system.

Label supporters, however, would object to the notion that genetically modifying organisms is in any way similar to selective breeding. Selective breeding, often referred to as crossbreeding or hybridizing, is a process that takes place in the wild, and can occur with or without the human influence. The act of splicing genes from one organism into the genes of an unrelated organism, a process called transgenesis, can only be done in a lab with the use of sophisticated technology. Thus, they may argue, the processes are nothing alike, and are therefore not comparable. And while it's true that the process of selective breeding and transgenics are not similar methods, focusing on the process misses the point. This line of reasoning assumes that the process of bioengineering is so drastically different from other methods of altering plant DNA that it must be isolated and segregated from the whole of agricultural techniques. Practically speaking, there is little justification for such a distinction. Writing for *Forbes* magazine, Henry Miller, Stanford University Hoover Institution Fellow and founding director of the FDA's Office of Biotechnology, observes that current genetic

modification techniques "are an extension, refinement ... an improvement ... on the kinds of genetic modifications that have long been used to enhance plants, microorganisms, and animals for food" (Miller). In other words, the process of genetically engineering is just another tool in the bag, one that should be viewed in the context of all the other tools. Of the many methods used by agriculture to achieve desirable traits in plants, none has been subjected to a legal requirement to notify consumers of the specific methods of production. Such a requirement makes little sense now, particularly when considered in the context of the scientific record regarding the health and safety of GE foods.

For label opponents, the questions of human health and safety are settled; genetic engineering has been proven safe by science, and labeling is therefore unnecessary. As Miller observes, "every major scientific and public health organization" who has studied the health impacts of biotechnology "from the American Medical Association to the National Academy of Sciences and dozens more" have all concluded that GE foods are "at least as safe, and probably safer, than conventional ones" (Miller). For instance, the American Medical Association has stated in no uncertain terms that "there is no scientific justification for special labeling" of genetically engineered foods (H-480.958). Further, a compendium published by the European Commission concluded that data aggregated from one hundred independent, peer-reviewed studies over the course of a decade "provide[s] at least equal assurance of the safety of these foods compared to conventional counterparts" (European 133). The European Union, it should be noted, is among the more stringent GE regulators in the world. Their consensus with the rest of the scientific community should demonstrate that there is very little ambiguity on the question of GE safety. The scientific record is clear; there is no discernable evidence to suggest that GMOs are harmful to humans

Due to the broad scientific consensus, the Food and Drug Administration, the federal

body appointed to regulate the safety of GE foods in the United States, finds no reason to impose labeling requirements onto food producers. Testifying before congress in 2014, former FDA director Margaret Hamburg said that the FDA "has not seen evidence of safety risks associated with genetically modified foods" (Hamburg qtd. by Pitts). Consequently, the FDA considers GE crops to be "substantially equivalent" to non-GE varieties, and GE crops are therefore "generally recognized as safe" (Federation). The FDA's position is important in this conversation because the agency's wealth of knowledge, experience, and access to data give it a privileged position from which to make highly informed judgements, making it a top authority on the subject. Currently, the agency has found no scientific justification for segregating GE foods from non-GE foods. The data simply isn't there, and this should be a major consideration as voters decide on Proposition 37.

And the lack of data is an important point, because without is, mandatory labeling is not supported by the law. According to Miller, the FDA has long required "labeling only to indicate that a new food raises questions of safety, nutrition, and proper usage" (Miller). Miller points out that the FDA's labeling jurisdiction is restricted to the regulation of health risks and statement accuracy. In other words, unless there are known health issues, or a company is intentionally or accidentally misleading consumers, the FDA has no legal cause to compel labeling. In fact, federal regulations explicitly prohibit labels "that could be misunderstood, even if they are strictly accurate" (Miller). Miller charges that the labels could be misinterpreted as warnings by consumers, and would thus be misleading, making them illegal. Miller notes that the FDA's interpretation has repeatedly been upheld by federal courts, which is important, because any label laws passed by California voters would need to withstand legal challenges to ever take effect.

Indeed, unless a public health risk exists, compulsory labeling may be unconstitutional. In

Vermont, a similar mandatory label law was found to violate the commercial free speech rights of affected corporations. In 1995, the State of Vermont enacted a statute requiring that dairy produced from cows treated with the genetically engineered growth hormone rBST must contain a label informing consumers of this fact (International 1). The International Dairy Association and others challenged the law, alleging that it violated their constitutionally protected commercial free speech rights. In International Dairy Association MIF v Amestoy, The United States Court of Appeals, Second Circuit agreed, finding that because the FDA had "concluded no appreciable effects" as a result of the added growth hormone, "and that there was no human safety or health concerns associated" with the same, the interests of the state were not sufficient "to justify compromising protected constitutional rights" (International 4). Specifically, the court found that the label requirement caused "irreparable harm" to the affected businesses because the law violated their right "not to speak" (International 3). In essence, the court held that for the state to be justified in compelling companies to label particular ingredients, there must exist a strong public interest beyond the simple desire to know. The passage of Prop. 37 would repeat the "irreparable harm" to the food industry in the same way the Vermont law harmed International Dairy. Label supporters must therefore show potential or demonstrated harm to gain the sympathy of the courts. The key point to note is that the absence of a discernable health risk actually ties the hands of government to act, even in the face of popular demand.

Supporters of labels would argue this point, suggesting an inherent "right to know" about every ingredient that is added into their food. This viewpoint holds that the people's right to be informed trumps a corporation's right not to speak. This argument is an allusion to John F. Kennedy's speech to congress introducing the "Consumers Bill of Rights," which extoled, among other rights, the "right to be informed" about the products consumers purchase (Kennedy). And while this is true for products that may present health and safety concerns, the

idea that companies must disclose every single piece of information relating to their production process has no basis in law. Indeed, in *International*, the court held that "consumer curiosity alone is not strong enough" to compel the state to "sustain the compulsion of even an accurate, factual statement" (International 5). The court held that because "compelled disclosure of 'fact' is no more acceptable than compelled discloser of opinion," the statue was "likely to be held unconstitutional" (International 5). The Consumers Bill of Rights will lose to the U.S.

Constitution every time, because the right to be informed is an idea that does not exist as a legal principle. The United States can no more compel corporations to speak than it can compel its citizens. The constitutional rights afforded to commercial free speech is comparable to those of a natural person's, and therefore the government has no constitutional grounds to mandate GMO labeling. Any labeling law passed in California will have to meet the standards set forth by the federal courts and the constitution. Otherwise, Proposition 37 will be headed toward a fate similar to the rBST labeling law of Vermont.

Supporters of mandatory labeling, however, consider a completely different set of evidence in forming their views on GMO labeling. They operate from a different set of principles and hold alternative interpretations of the available data. For instance, those who support labels cast doubt on the FDA's ability and willingness to prove its assertions regarding to the safety of genetically engineered varieties in the food supply. Due to the FDA's "substantially equivalent" stance, the FDA has no cause or justification to suspect any health or safety risks from new GE foods as they reach the market. Consequently, GE foods are not are not required to undergo any specialized testing before reaching the market. According to federal guidelines, foods that are "generally recognized as safe" are not subjected to pre-market approval (Federation). In fact, there is no difference in the way the FDA treats GE and non-GE plants ("Questions"). Indeed, the process of testing new GM foods is strictly voluntary and, when safety trials are conducted,

FDA guidance clearly states that "it is the food producer who is responsible" for health and safety testing ("Guidance"). To label supporters, this voluntary, self-reporting requirement does not meet the standard of responsible food regulation. What assurances do the public have of the safety of GE products under such a system? Very little, other than the promises of companies who stand to lose money if their products are not approved. The FDA, then, lacks credibility in the eyes of those who feel that the agency has not done enough to ensure the safety of the food supply.

Compounding concerns of lax federal enforcement, supporters of labels assert that, even when products are subjected to rigorous approval by the FDA, their safety is not a certainty. This fact was highlighted by a 1990 report by the General Accounting Office that sought to study the effects of drugs whose risks became known only after approval. The report found that, of 198 drugs approved between 1976 and 1985, "102, or 51.5%", had serious post approval risks, evidenced by label changes or withdrawals from the market. (United States "FDA"). A key difference between the approval processes of GE food and that of medication is that the approval process for new drugs is not voluntary. Even rigorous testing of new products doesn't guarantee their safety. With the dearth of pre-market safety testing, post-approval risk for genetically engineered organisms is a distinct possibility. Hence, supporters of Prop. 37 and similar laws do so not out of certainty of available science, but what they believe to be reasonable doubt concerning the safety of GE foods.

Some readers may correctly note that the GAO study referenced above applies to new drugs released onto the market, rather than their generic counterparts. This is an important distinction because, unlike the generic version of a drug, which is "substantially equivalent" to the name-brand version that has already been thoroughly tested, new drugs obviously carry more risks simply by virtue of being new. Thus, skeptics would argue, the comparison between the

post-approval risk of new drugs and that of "substantially equivalent" GE plants is not applicable. However, it is reasonable to suggest that at least some GE varieties are not substantially equivalent to their natural counterparts. For instance, Monsanto's Bt corn is engineered with a naturally occurring bacterial toxin found in soil (Bessin). Scientists have essentially converted the corn into a pesticide; when the bugs eat the corn, they die. Because this bacteria is not naturally found in corn, the new corn containing Bt is substantially *different* from any known variety of corn on the planet. The plant is so different, in fact, that it is regulated not as a food by the FDA, but as a bio-pesticide by the Environmental Protection Agency (U.S. Food"). This fact alone should merit some sort of label alerting consumers to the fact that they may be consuming pesticide, especially considering prevalence of corn in todays processed food industry.

The knowledge that the line between food and pesticide has been blurred, at the very least, raises concerns about the safety of GE foods as it relates to human health. Regarding the safety of Bt corn, the FDA defers to the EPA. In a statement regarding Bt corn, the FDA states that it "does not believe" that the corn poses any long term health effects "based on the EPA's findings" that "genetically engendered ... proteins are safe" ("U.S. Food"). According to the EPA, the Bt toxin "pose[s] no significant risk" to human health (Mendelsohn 1005). Accordingly, The EPA doesn't require long-term testing because the "protein instability in digestive fluids ... eliminate[s]... the need for longer-term study" (Mendelsohn 1005). In other words, the current consensus is that Bt protein breaks down in the human gut, and is thus harmless. But there are indications that this this is not always the case. In one study, published in *Reproductive Toxicology*, scientists at the Clinical Research Centre of Sherbrooke University Hospital Centre in Quebec, Canada found traces of the Bt toxin in the blood and umbilical cords of 28 out of 30 pregnant women tested, and 27 of 39 of non-pregnant women tested, which amounts to a 98%

and 67% detection rate, respectively (Aziz). Granted, the sample size is small, but the study is significant because, as the authors note, theirs is the first known study to "highlight the presence of pesticides-associated genetically modified foods in maternal, fetal and non-pregnant women's blood" (Aziz 5). And while a three generation study of rats published in *Food and Chemical Toxicology* found Bt to have no negative impact, "statistically significant" changes to the amount of creatinine, globulin, and "total protein produced" were discovered (Kılıc 1168). While these changes do not necessarily reflect any adverse health effects, the results of the two studies do suggest that the Bt toxin does not completely break down in the gut, as is suggested by the EPA, and that it can indeed result in physiological changes. These findings further case doubt on the absolute statements of GE safety made by the authorities.

It is this climate of uncertainly that is a main driver in the push for increased transparency of GMO foods. The push for labeling, then, it is not about an opposition to science, but the desire to make better use of science to allow consumers to make more informed decisions about the foods they put into their bodies. What other minor chemical changes could Bt or other GE varieties cause over the long term? What type of unintended consequences can occur from such minor changes in total protein? Can these small changes compound each other and worsen over time? Without rigorous long term testing, how can we find out? These are questions that have yet to be answered, and without sustained long term studies on humans, it may be impossible to know. Given these types of health considerations, supporters of labels feel that they have a right to make informed decisions regarding the food they eat. Informed decisions require access to the relevant information, which of course depends on some degree of cooperation and transparency on the part of the food producers. Thus, the movement to label GMO foods is one that seeks a level of corporate transparency that is in line with the values of health conscious consumers.

But consumer values of transparency are not shared by many of the largest names in the

biotech industry, and this difference in values puts the goals of health conscious consumers in direct conflict with the goals of the industry. For this reason, a common argument put forth in favor of labeling is one made in opposition to Monsanto, the world's largest seed and chemical company and, for better or worse, the face of biotechnology. Label supporters equate the business model and actions of Monsanto with the science of GMO. In this way, opposition to Monsanto translates into opposition to GM foods in general, which translates into support for labels. Skeptics may object to such a line of reasoning, arguing that it amounts to little more than an argumentum ad monsantum, a lapse in logic where one assess the science of biotechnology as a whole based upon the behaviors and practices of a single company. However, considering the disturbing trend of behavior by the world's most influential producer of GE goods, as well as the large amount of influence the company wields, an argument against Monsanto is not completely unreasonable.

Not only has the biotech firm shown itself to be indifferent to consumers' health concerns regarding its products, it has demonstrated hostility toward consumer efforts to gain transparency. Indeed, speaking to *New York Times* reporter Michael Pollan in 1998, Monsanto's then Director of Corporate Communications, Phil Angell, said that "Monsanto should not have to vouchsafe the safety of biotech food ... Our interest is in selling as much of it as possible.

Assuring its safety is the FDA's job" (Angell qtd. by Pollan). Clearly, this contradicts the FDA's position that "[u]ltimately, it is the food producer who is responsible for assuring safety" ("Guidance"). Today's internet savvy consumers know when they're getting the runaround.

Monsanto's refusal to vouch for the safety of its own products is even more troubling when its hostility to labeling is considered. According to *The Guardian* newspaper, Monsanto and other biotech firms combined to spend over \$45 million dollars to defeat Proposition 37 in 2012 (Goldenberg). This aggressive response to consumer demands for transparency is curious indeed,

leading many to question the reasons for such an abject refusal to disclose.

To better understand the opposition to Monsanto and the company's role in the genetically engineered food discussion, it is important to briefly examine some of Monsanto's more well-known products. Even people who have never heard of Monsanto have likely heard of at least one of its chemicals, such as the banned herbicide, Agent Orange, which was used by U.S. forces as a weapon during the Vietnam war (Westing 342). Today, Monsanto's leading chemical is a product marketed under the name "Roundup," and is currently the most widely used herbicide on the planet (Cressy). Roundup is sold to both agricultural and domestic markets. Considered safe to humans for decades, Roundup's key ingredient, glyphosate, has been recently linked to non-Hodgkin lymphoma in humans, and tumors in rats, leading the World Health Organization to reclassify glyphosate as "probably carcinogenic to humans" (Cressy). Another of Monsanto's most profitable products is its line of "Roundup Ready" crops which are engineered specifically so that crops can survive higher and higher amounts of the powerful herbicide. According to a Massachusetts Institute of Technology factsheet on Roundup Ready varieties, "[c]urrent ... crops include soy, corn, canola, alfalfa, cotton, and sorghum, with wheat under development" (Delano).

Taken together, the company's shaky health record, its laissez faire approach to product safety testing, and its abject hostility toward transparency make it difficult to trust its proclamations of overwhelming safety regarding its products. Label supporters see an industrial chemical company who deals largely in carcinogens; a company that employs a business strategy that, in part, relies on bioengineering plants to be able to withstand higher amounts of the chemicals it sells, thus enabling it to sell more chemicals. Due to the company's history and what the record has shown about its chemicals thus far, the safety of Monsanto's entire product line is in question. These lingering questions are magnified by the company's culture of secrecy and

absolute refusal to acquiesce to any amount of public scrutiny, leaving the public in a place deep mistrust. Consumers want to know if they are eating a pesticide, or if their food was engineered to withstand high doses of probable carcinogens. Without the relevant information, it is impossible to make healthy decisions where these products may, or may not be, concerned. Therefore, if the FDA and the biotechnology industry are unwilling to provide consumers with the ability to make informed choices, it is up to voters to enact the language of Proposition 37 as a means of protecting the health of themselves and their families.

The current public tide against companies like Monsanto is one reason that even some in the pro-GMO community are calling for more transparency. Writing for *Scientific American*, Dan Fagin recognizes the damage companies like Monsanto are inflicting on the public perception of the science of GMO itself. He observes that this is largely due to the fact that "secrecy is a key driver of risk perception heuristics: When information is being withheld from us, we immediately assume the worst" (Fagin). Fagin notices, like many, that the abject refusal by the industry to disclose to the public creates a deep well of mistrust. The GE industry is facing a public crisis of perception. Clearly, the momentum favors transparency. As Fagin reluctantly admits, labeling is going to happen. It's only a matter of time (Fagin). If the industry embraces labeling, perhaps work can be done to bridge the gap between the public and the producers of its food supply. After all, the manner in which society approaches this issue of food supply should not be adversarial, but one of community partnership.

The issue of GMO labelling is not one that will be going away any time soon. Currently, Americans are united in their belief that GE foods should be labeled (Langer). Unfortunately, public opinion is not a sufficient mover of public policy, as the political power of the public varies from state to state. Genetic engineering is where food is going. I recognize its potential and have no doubt humanity will someday obtain mastery of the technology. But today, the

question for me is how much control should society grant to a handful of secretive multi-national corporations; those few who have been entrusted with the rights to manipulate, patent, and own an ever-growing portion of the global food supply? There is no amount of scientific data that will help me trust a company who turns my food into pesticide and treats me like an enemy for wanting to know about it. The fact that an unproven and untested technology was imposed upon the American population without discussion or debate is alarming in itself. But the ferocity with which the industry meets popular calls for information is unnerving. My experience has been that when someone is hiding something, it's because they have something to hide; this axiom holds especially true for the corporate-industrial complex. Just ask R.J. Reynolds. Fortunately for citizens of California, we do have the political clout to affect change. If the industry is unwilling to disclose, then it is up to the public and its representatives in government to mandate it. As responsible stewards of our society and its precious food supply, we should accept nothing less than full disclosure. Which is why I support Proposition 37.

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