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HOW AMERICA CAN MOVE CLOSER TOWARD MANDATED LABELING FOR GENETICALLY MODIFIED FOODS AND REMAIN FIRST AMENDMENT COMPLIANT

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I. INTRODUCTION

Genetic modification is commonly referred to as recombinant DNA (rDNA) technology.[1] First developed in the 1970s by Cohen

[1] Earle Nestmann et al., *The Regulatory and Science-Based Safety Evaluation of Genetically Modified Food Crops – A USA Perspective, in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 1, 1 (Keith T. Atherton ed., 2002).

and Boyer who successfully connected two different pieces of DNA, rDNA technology is used to insert genes into various crop species to enhance or create desirable agronomic traits.[2] Through traditional plant breeding, crop improvement is accomplished by selecting the highest quality plants and seeds, and saving them for planting the following year.[3] Traditional plant breeding can only take place between two plants with the ability to sexually mate with each other.[4] Through this mechanism, the new traits are limited to those present in the original species.[5] Unlike traditional plant breeding, genetic engineering is not bound by species-specific DNA limitations.[6] rDNA technology is used to merge the DNA of different species, which can lead to the creation of unstable combinations of plant, animal, bacterial, and viral genes that do not occur in nature or through traditional crossbreeding.[7]

The relatively basic five-step process is described as follows. First, all of the DNA is extracted from the desired organism simultaneously, but scientists do not use every single one of the organism's genes. Only the genes of interest are used.[8] The extracted genes of interest are then cloned, and the next step of the process is the creation of thousands of copies of that specific gene of interest.[9] The third step is designing the gene of interest to work once it is inside a different organism.[10] The gene is cut apart using enzymes to replace the gene regions that have been separated.[11] Once the gene

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[2] Alan McHughen & Stuart Smyth, *US Regulatory System for Genetically Modified [Genetically Modified Organism (GMO), rDNA or Transgenic] Crop Cultivars*, 6 PLANT BIOTECHNOLOGY J. 2, 3 (2008).

[3] University of Nebraska-Lincoln, *Overview of the Process of Plant Genetic Engineering*, AG BIOSAFETY, http://agbiosafety.unl.edu/education/summary.htm (last visited Nov. 4, 2013).

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *GMO Facts*, The Non-GMO Project, http://www.nongmoproject.org/learn-more/ (last visited Nov. 4, 2013).

[8] *University of Nebraska-Lincoln, supra* note 3.

[9] *Id.*

[10] *Id.*

[11] *Id.*

has been modified, it is ready for the fourth step–transformation, or gene insertion.[12] Because of the millions of cells contained in a single plant specimen, it would be impossible to insert the copied transgene into every single cell.[13] Thus, scientists utilize tissue culture to create masses of undifferentiated plant cells called a callus.[14] These cells receive the new transgene.[15] There are various methods employed to insert new genes into the cells, including agrobacterium, gene guns, microfibers, and electroporation.[16] Regardless of the method employed, the purpose is to deliver the new gene into the nucleus of a cell without killing or damaging the cell.[17] The transformed cells are regenerated into transgenic plants that are then grown to maturity inside greenhouses.[18] The seeds produced through this process have inherited the transgene and the work of the genetic engineer is complete.[19] The transgenic seeds then enter the fifth stage of the process, which is backcross breeding.[20] Traditional plant breeding methodology is used to combine the traits of the elite parents and the selected transgene into a single line.[21] The offspring is then repeatedly crossed-back into the elite line to obtain a high yielding transgenic line.[22] The goal of backcross breeding is to yield a line that is as identically close as possible to the recurrent parent with the addition of the new transgene.[23]

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[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] Chad Geater & Thomas Prest, *Backcrossing – Basics*, GENETIC TECHNOLOGY SUPER WORKSHOP (Feb. 3, 2010), http://www.seedtechnology.net/docs/Backcross%20Breeding%20-TP%202-3-2010.pdf.

II. rDNA TECHNOLOGY REGULATION

Rather than establishing a new government agency or division to oversee the regulation of products and plants developed through rDNA technology, the United States decided it would apply its preexisting regulation structure to this novel technology.[24] The USA relies on developers and breeders to exercise their own due diligence in evaluating their own crops.[25] The first regulatory agency to publish their interest in evaluating the safety of rDNA technology was the National Institutes of Health (NIH).[26] A division of the U.S. Department of Health and Human Services, the NIH is the nation's medical research agency and the largest source of funding for medical research in the world.[27] Until 1978, the release of organisms that had been modified by rDNA technology in the U.S. was prohibited unless otherwise personally approved by the NIH director.[28]

The NIH created the rDNA Advisory Committee (RAC) to review the latest rDNA technology, review applications of the technology, and to make recommendations for establishing research guidelines.[29] In 1983, the first rDNA organism to be approved for environmental release based on the RAC's guidelines was a type of pseudomonas bacteria.[30] An immediate backlash against the NIH ensued for failing to prepare an assessment of the potential environmental impact prior to the release of the organism.[31] After this controversy, the NIH was relieved of its responsibility to regulate the environmental release of genetically modified organisms.[32] However, the NIH's guidelines are still employed today when

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[24] McHugen & Smyth, *supra* note 2, at 3.

[25] *Id.*

[26] Nestmann et al., *supra* note 1, at 2.

[27] *About NIH*, NATIONAL INSTITUTES OF HEALTH, http://www.nih.gov/about/ (last reviewed Sept. 18, 2013).

[28] Nestmann et al., *supra* note 1, at 2.

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

assessing the safety of rDNA technology and products.[33]

In 1986, the Office of Science and Technology Policy (OSTP) developed a "Coordinated Framework for Regulation of Biotechnology," which provided a clearer vision of how federal regulatory agencies were to be involved with evaluating the safety of products using rDNA technology.[34] The three agencies assigned to regulate products using rDNA technology were the US Food and Drug Administration (US FDA), the US Department of Agriculture (USDA), and the US Environmental Protection Agency (US EPA).[35] The OSTP concluded that rDNA does not possess inherent risks, and that rDNA regulation should focus on the risk of the actual product itself, and not the process that is used to develop the product.[36] Thus, the U.S. government has retrofitted existing legislation that was never designed to encompass these types of novel biotechnology products.[37]

The decision not to create all new legislation to regulate the biotechnology industry is in stark contrast to the way other countries, for example, the European Union, have chosen to regulate genetically modified organisms (GMOs).[38] Since April 18, 2004, all food products in the European Union containing genetically modified (GM) ingredients must be labeled as such.[39] Dubbed "Frankenstein Food" by the European public, GMOs have been largely shunned in Europe, which is in sharp contrast to the general acceptance or ignorance of GMO technology by the American general public.[40] Even his Royal Highness, Charles, Prince of Wales, has commented on the topic:

> Genetic modification takes mankind into the realms that belong to

[33] *Id.*

[34] *Id.*

[35] *Id.* at 3.

[36] McHugen & Smyth, *supra* note 2, at 4.

[37] *Id.*

[38] Nestmann et al., *supra* note 1, at 4.

[39] Petra Tenbult et al., *Categorizing Genetically Modified Food Products: Effects of Labeling on Information Processing*, 109 BRITISH FOOD J. 305, 305 (2007).

[40] John Stephen Fredland, *Unlabel Their Frankenstein Foods: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically-Modified Organisms*, 33 VAND. J. TRANSNAT'L L. 183 (2000).

> God, and to God alone. Apart from certain highly beneficial and specific medical applications, do we have the right to experiment with, and commercialize, the building blocks of life? We live in an age of rights – it seems to me that it is time that God had some rights too.[41]

A primary fear voiced by the Europeans is a concern for the ecological consequences of introducing strange organisms into their ecosystem.[42] In 1998, an experimental field of genetically modified oilseed rape cross-pollinated nearby non-GMO plants.[43] The British Agriculture Ministry acted swiftly, ordering the destruction of the experimental field to prevent the creation of a new breed of "super weed," which could render entire fields either sterile or invulnerable to normal chemicals.[44] Another main concern of the Europeans is the potential health risk of the consumption of genetically modified products.[45] It was recognized that GMOs could elicit new allergic responses and upset the balance of microbes in the human digestive system.[46]

The National Research Council (NRC), an operating arm of the National Academy of Sciences (NAS) has functioned as the primary advisory source of the safety evaluation of rDNA developed products in the U.S.[47] In 1987, the NAS released a report expressing the position that products using rDNA technology did not pose any unique risks when compared with products developed through more conventional means of genetic modification.[48] The conclusions of this report entitled, "Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues", are still referenced by developers and regulators of GM crops worldwide.[49] In 2000, the NRC published "Genetically Modified Pest-Protected Plants: Science

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[41] J. Derek Bewley, *Seeds of Hope; Seeds of Conflict*, *in* BIOLOGY OF SEEDS: RECENT RESEARCH ADVANCES 1, 7 (Gregorio Nicolas et al. eds., 2003).

[42] Fredland, *supra* note 40, at 185.

[43] *Id.*

[44] *Id.* at 187-188.

[45] *Id.* at 188.

[46] *Id.*

[47] Nestmann et al., *supra* note 1, at 4.

[48] *Id.*

[49] *Id.* at 5.

and Regulation."[50] This report contained requests for better coordination between agencies to strengthen the regulatory approval process, establish on-going monitoring of environmental and human health impacts, and increased access to the information used by the regulatory agencies in decision making.[51] Today, it is the FDA that has the main task of regulating the approval and requirements of GMO technology with regard to the American food supply.[52]

In 1986, the FDA first asserted that it had the authority to regulate genetically modified foods under either § 402(a)(1) of the Federal Food, Drug and Cosmetic Act, or under the food additives clause of § 409.[53] This was a pivotal time because genetically modified foods could either be regulated as though they had additives, or as though they had been adulterated.[54] The additive clause of § 409 mandates that food producers file a "food additive petition" before marketing the foods containing the additive.[55] This method of regulation requires a heightened safety standard, requiring producers to perform extensive safety testing to demonstrate that if used as intended, their additive can be used with "reasonable certainty of no harm."[56] However, the FDA more commonly regulates and recalls whole foods through their authority under the adulteration clause.[57] Regulation under the adulteration clause provides the food producers with a much looser standard. Section 402 states: "It is the responsibility of the producer of a new food to evaluate the safety of the food and assure that the safety requirement of § 401(a)(1) has been met."[58] The first genetically modified food crop to receive approval was Calgene's Flavr Savr ™

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[50] *Id.*

[51] *Id.*

[52] *Id.* at 5-6.

[53] David L. Pelletier, *Science, Law and Politics in the Food and Drug Administration's Genetically Engineered Foods Policy: FDA's 1992 Policy Statement*, 63 NUTRITION REVS. 171, 173 (2005).

[54] *Id.*

[55] *Id.*

[56] *Id.*

[57] *Id.*

[58] *Id.*

tomato in 1994.[59] In 2011, 88% of all corn and 94% of all soybeans grown in the U.S. were grown using genetically engineered seeds.[60] According to some estimates, it is possible that up to 70 percent of foods on American grocery store shelves contain genetically engineered ingredients.[61]

Currently, the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) covers U.S. general food labeling rules. The FDCA's affirmative labeling requirements include: 1.) a statement of identity with either the common or usual name of the food, or an appropriately descriptive term; 2.) a net contents statement; 3.) a statement containing the manufacturer's name and address (responsibility statement); 4.) a list of the product's ingredients; and 5.) a statement containing the nutritional value of the product.[62] The required labeling information must also be in a specific format with regard to package location and type size.[63] Five main categories of information must always be listed on a food's label as part of the "Nutrition Facts" panel: calories, fat, carbohydrates, sodium, and protein.[64] America has a strong general labeling precedent, particularly with regard to our foods.

III. THE BIOTECHNOLOGY NARRATIVE

The biotech narrative has promised that GMOs will improve pesticide resistance while reducing the need for pesticides, and increasing yields.[65] However, reputable studies have shown that the biotech narrative may not be measuring up to these promises.[66] Dr.

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[59] Tessa DeCarlo, *Tasting the Flavr Savr*, WALL ST. J., Aug. 3, 1994, at A8.

[60] DEBRA BOWEN, CALIFORNIA GENERAL ELECTION – OFFICIAL VOTER INFORMATION GUIDE 54 (2012).

[61] *Id.*

[62] Krista Hessler Carver, *A Global View of the First Amendment Constraints on FDA*, 63 FOOD AND DRUG L.J. 151, 153 (2008).

[63] *Id.*

[64] *Id.* at 154.

[65] Charles M. Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the U.S. – The First Sixteen Years*, *24 ENVTL. SCI. EUR.* 1, 1-2 (2012).

[66] *See id.*

Charles Benbrook of Washington State University has found that the use of herbicides has actually increased instead of decreased in three genetically modified crops: cotton, soybeans, and corn.[67] The tougher-to-control weeds have required a staggering increase in volume of herbicide required to deal with weed problems.[68] In 1999, only 1.5 million pounds of herbicide was used to deal with tougher to control weeds.[69] In contrast, about 90 million pounds of herbicide was used in 2011.[70] This is a shocking and undeniable increase in herbicide use. Not only are GMOs requiring the use of more chemicals, but exorbitant herbicide use needs to be addressed in a meaningful and timely way for the safety of the American public.

A. Gene Flow Matters

Another oft heard argument from biotech corporations is that we should not be concerned about the escape of transgenes from genetically modified crops, as GMOs have been designed specifically for GM systematic farming and should not be able to thrive in the wild. However, bioethicists have been concerned with these assertions since the inception of GMO technology.

In 2002, bioethicist Dr. Allison A. Snow wrote an insightful article urging caution and prudence with regard to potential gene flow.[71] Dr. Snow noted that genetic engineering raises concerns because it enables the spread of novel fitness traits into ecosystems, and into many different types of crops, each with a unique outcross potential.[72] Genes that are newly introduced could potentially disperse into nearby populations, bringing along new phenotypic traits.[73] "[W]hen novel genes spread to free-living plant populations, they have the potential to create or exacerbate weed problems by

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[67] Brian Clark, *More Weed Resistance Means More Pesticide Used*, WSU NEWS (Nov. 13, 2012), http://wsunews.wsu.edu/pages/publications.asp?Action=Detail&PublicationID=33169.

[68] *Id.*

[69] *Id.*

[70] *Id.*

[71] *See* Allison A. Snow, *Transgenic Crops – why gene flow matters*, 20 NATURE BIOTECHNOLOGY 542, 542 (2002).

[72] *Id.*

[73] *Id.*

providing novel traits that allow these plants to compete better, produce more seeds, and become more abundant."[74] Snow went on to say: "[A] gene is a gene, and our limited experience from environmental studies confirms that transgenes disperse and become incorporated into the genomes of other species in the same manner as other crop genes . . . . [G]ene flow can be surprisingly widespread."[75] At the time of Dr. Snow's article, she noted that it was difficult to find peer-reviewed publications with relevant data, due to a lack of funding, and lack of interest from government programs that sponsor agricultural research grants.[76] Dr. Snow noted that the need for environmental studies is imperative because it is impossible to prevent gene flow between sexually compatible species in the same area.[77]

Eight years later, Dr. Cynthia Sagers, a professor of biological sciences at the University of Arkansas, spotted a patch of robust looking canola flowers while driving along a North Dakota roadway for a different scientific study.[78] Dr. Sagers quickly recognized that though "they spray these roadsides with herbicides, [the] canola . . . [was] the only thing still growing."[79] Next, Sagers decided that every five miles along their journey, she and her assistant would stop and take a sample of the roadside plants to later test for recombinant DNA–the hallmark of GM crops.[80] Of the 3,000 miles traveled to complete the sampling, 83 percent of the canola Sagers tested was found to contain transgenic material.[81] Sagers concluded that tens of thousands of unharvested acres of canola contribute to the proliferation of GM canola into wild populations.[82] Additionally, Sagers noted that although this discovery was made in North Dakota,

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[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] University of Arkansas Newswire, *First Wild Canola Plants With Modified Genes Found in United States* (Nov. 6, 2012), http://newswire.uark.edu/article.aspx?id=14453.

[79] *Id.*

[80] *Id.*

[81] *Id.*

[82] *Id.*

there are worldwide implications: "Things can escape from cultivation, and we need to be careful about what we stick into plants."[83] Whether from pollen drift or human-induced commingling, the USDA has also acknowledged that plant breeding may result in the mixing of genes and gene products from unintended plant sources.[84]

Not only are there bioethical issues surrounding the proliferation of GM crops into unintended areas, but major legal issues are also at play. For a farmer to legally grow a Monsanto crop, the farmer is required to license the seeds from Monsanto and renew that license annually.[85] Monsanto has filed hundreds of suits against farmers whose own non-GMO crops have become involuntarily contaminated by Monsanto's seeds.[86] Monsanto has successfully brought numerous patent infringement lawsuits against hundreds of farmers who maintain the position that their crops were, without their knowledge or consent, contaminated by Monsanto's seeds.[87] The damages have been so devastating that some farmers have even lost their farms over these types of lawsuits.[88] Allowing Monsanto to successfully collect damages on these types of contamination claims is bad policy. Current U.S. policy essentially incentivizes Monsanto and its industry brethren to pollute other non-GM farmer's crops. Corporations are escaping liability by not having to pay damages from polluting and contaminating the environment, while simultaneously being financially rewarded when their GM seeds contaminate a neighboring farmer's non-GMO crops. For example, GM plants grown on Monsanto-licensed farms are being used as weapons to wipe out the surrounding organic and natural crop competition.

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[83] *Id.* at 2-3.

[84] A. Bryan Endres & Michaela N. Tarr, *United States Food Law Update: Initial Food Safety Restructuring Efforts, Poultry Production Contract Reforms and Genetically Engineered Rice Litigation,* 6 J. FOOD L. & POL'Y 103, 133 (2010).

[85] Oscar Michelen, *Solo Farmer Fights Monsanto and Wins Over Patented Seeds*, COURTROOM STRATEGY (Dec. 7, 2012).

[86] *Id.*

[87] *Id.*

[88] *Id.*

However, Monsanto challenged the wrong farmer in Percy Schmeiser. A Canadian farmer of 50 years, Schmeiser's organic Saskatchewan farm became contaminated by Monsanto's GM canola.[89] Schmeiser discovered his plants were contaminated when he sprayed a three-acre test patch of his farm located near the road with Roundup.[90] He found that 60% of the plants survived, indicating those remaining plants contained Monsanto's patented genes and cells.[91] When Monsanto found out that some of their seeds were growing on Schmeiser's non-licensed farm, Schmeiser was threatened and intimidated, and they even tried to take away his land.[92] But when Monsanto filed suit, Schmeiser was indignant and in true David and Goliath form, filed a counterclaim for crop contamination.[93] The case of *Percy Schmeiser v. Monsanto Canada Inc.* made it all the way to the Supreme Court of Canada.[94] The main issue was whether Schmeiser "used" the patented gene or cell, thus infringing on Monsanto's patent.[95] The Canadian Court held that the onus of proving infringement lies with the plaintiff Monsanto.[96] But did Schmeiser's activity deprive Monsanto in whole or in part, directly or indirectly of full enjoyment of the monopoly conferred by law?[97] The Court held that inventors are normally deprived of the fruits of their invention and the full enjoyment of their monopoly when another person, without license or permission, uses that invention in furthering a business interest.[98] Because the court could not find that Schmeiser had engaged in any activity with Monsanto's product deliberately, or to further his own commercial interests, the

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[89] Schmeiser v. Monsanto Canada Inc., et al., 2004 SCC 34 (Can.).

[90] *Id.*

[91] *Id.* at para. 6.

[92] Michelen, *supra* note 85.

[93] *Id.*

[94] *See* Schmeiser, 2004 SCC 34.

[95] *Id.* at para. 28.

[96] *Id.* at para. 29.

[97] *Id.* at para. 43-44.

[98] *Id.* at para. 37.

court held that he did not commit an infringing use.[99]

The United States is also dealing with its fair share of litigation of this type as well. Riceland Foods–the largest rice cooperative in the U.S.—won its suit against Bayer Corporation when its natural long-grain rice was contaminated by Bayer's GM rice.[100] Bayer CropScience was also ordered to pay a dozen Arkansas farmers close to $50 million for damage done to rice prices due to the escape of their GM rice strain.[101] When countries in the European Union heard about Bayer's contamination with their unapproved, experimental GM rice, member countries refused to purchase US long-grain rice, which ultimately cost American farmers $389 million in projected sales, as well as cleanup costs.[102]

IV. THE FDA'S CURRENT APPROVAL PROCESS

Currently the FDA's guidance documents do not establish legally enforceable responsibilities upon biotech companies seeking to commercialize a GMO.[103] In 1992, the FDA published a "Statement of Policy: Foods Derived From New Plant Varieties.[104] Per this policy, though evaluation of GM crops is recommended, it is not a requirement.[105] The FDA also took the policy position that rDNA modification is not a "material fact" with regard to the FDCA and as such, rDNA foods are not required to be labeled.[106] Though "even small modifications in the structure of a protein can drastically alter its biological activity," the FDA's position is that GM proteins are

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[99] *Id.*

[100] Martinne Geller, *Bayer ordered to pay $136.8 mln in U.S. rice case*, REUTERS (Monday, Mar. 21, 2011) http://www.reuters.com/article/2011/03/21/idUSN2129802520110321.

[101] Michelen, *supra* note 85.

[102] *Id.*

[103] *See* Brian Tokar, *Deficiencies in Federal Regulatory Oversight of Genetically Engineered Crops*, ENVIRONMENTAL COMMONS (June 2006), http://environmentalcommons.org/RegulatoryDeficiencies.html.

[104] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22, 984 (May 29, 1992).

[105] Tokar, s*upra* note 103.

[106] Alliance for Bio-integrity v. Shalala, 116 F.Supp. 2d 166, 170 (D.D.C. 2000).

quite similar to or the same as naturally occurring proteins commonly found in food.[107] The agency announced it would presume that foods produced through rDNA processing would be "generally recognized as safe" (GRAS) under the Federal Food, Drug and Cosmetic Act ("FDCA").[108] Feeds and foods that are identical or nearly identical to their non-genetically modified counterparts are not deemed to be adulterated and thus do not trigger FDA review even if they were created through rDNA technology.[109] Genetically engineered traits can be classified as "novel proteins."[110] This allows biotech companies to withhold all information about the properties of the proteins – even their general nature, including potential toxicity to humans or other wildlife.[111] The practical result is that biotech companies have largely been left to regulate themselves.[112] The U.S. Government does not conduct any independent testing of biotech crops before they are approved.[113] Genetically engineered crops are merely subjected to "voluntary consultations" with biotech companies who can choose to consult the FDA about their new products.[114] Due to the voluntary nature of this process, the FDA bases its approval decisions on whatever testing the biotech company itself has chosen to perform and share.[115]

At the end of the process, the FDA sends a memo indicating whether the new food or feed is different in composition from its non-genetically modified counterpart.[116] An approval letter from a

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[107] *Id.*; Brian Tokar, *Addendum to Briefing Report: Deficiencies in Federal Regulatory Oversight of Genetically Engineered Crops*, INST. FOR SOC. ECOLOGY BIOTECHNOLOGY PROJECT (June 29, 2006), *available at* http://environmentalcommons.org/RegulatoryDeficiencies2.pdf.

[108] *Alliance for Bio-integrity*, 116 F.Supp. 2d 166, 170 (D.D.C. 2000).

[109] McHugen & Smyth, *supra* note 2, at 7.

[110] Tokar, *supra* note 103, at 5.

[111] *Id.* at 3.

[112] *Id.* at 1-3.

[113] Carey Gillam, *Mainstream Science Questions GMO Safety and Lack of Testing*, REUTERS (Nov. 14, 2012), http://laudyms.wordpress.com/2010/04/14/mainstream-science-questions-gmo-safety-and-lack-of-testing/.

[114] Tokar, *supra* note 103, at 6.

[115] *Id.*

[116] McHugen & Smyth, *supra* note 2, at 9.

Director of the Office of Premarket Approval at the FDA to a Regulatory Affairs Manager at Monsanto illustrates the typical back-and-forth between a biotechnology company and the FDA regarding the approval of a GMO:

> [I]t is our understanding that Monsanto has concluded that corn grain (kernels) fodder and silage derived from the new varieties are not materially different in composition, safety, and other relevant parameters from corn grain (kernels), fodder and silage currently on the market, and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA . . . Based on the information Monsanto has presented, we have no further questions concerning corn containing transformation events MON 802, 805, 830, 831, and 832 at this time. However, as you are aware, it is Monsanto's responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.[117]

Furthermore, it is difficult for producers to adopt labeling that advertises their product is GMO free, because the FDA has imposed strict limitations on voluntary labeling of non-GM foods.[118] For example, the FDA has stated that claims such as "not genetically modified" and "GMO free" are misleading, and that such voluntary claims need to be substantiated, which can be cost prohibitive for a food producer or manufacturer.[119] Thus far, the FDA's decision to not mandate the labeling of GM foods remains upheld.[120]

In *Alliance for Bio-Integrity v. Shalala*,[121] a coalition of individuals and various groups brought action to protest the FDA's 1992 policy

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[117] Letter from Alan M. Rulis, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, FDA to Dr. Kent Croon, Regulatory Affairs Manager, Monsanto Company, Sept. 25, 1996 *available at* http://www.fda.gov/Food/Biotechnology/Submissions/ucm161106.htm.

[118] Neil D. Hamilton, *The Law of Food: Eight Questions Shaping America's Food Policy*, ST. & LOC. FOOD POL'Y PROJECT 5 (Nov. 11, 2012), http://www.statefoodpolicy.org/docs/policy.pdf.

[118] Aurora Paulsen, *Catching Sight of Credence Attributes: Compelling Production Method Disclosures on Eggs*, 24 LOY. CONSUMER L. REV. 280, 288 (2011).

[119] Aurora Paulsen, *Catching Sight of Credence Attributes: Compelling Production Method Disclosures on Eggs*, 24 LOY. CONSUMER L. REV. 280 (2011).

[120] *Id.* at 288.

[121] Alliance for Bio-Integrity, 116 F. Supp. 2d 166 (D.D.C. 2000).

on genetically modified foods.[122] Some of the plaintiff's major claims were that the FDA did not engage in a formal notice-and-comment process when developing their rDNA policy statement, the FDA failed to prepare an Environmental Impact Statement or Environmental Assessment, the FDA's presumption that rDNA produced foods are GRAS, and therefore should not require a food additive petition under 21 U.S.C. § 321 was arbitrary and capricious, and that the FDA's decision to not require labeling for rDNA foods is arbitrary and capricious in and of itself.[123]

In this key decision the court developed many important holdings that have seriously impacted the American food supply as we know it today. Because the FDA did not implement formal actual notice and comment procedures, the court focused on the formal publication of the FDA's statement of policy.[124] The court held that because Congress had passed a variety of statutes (the Administrative Procedure Act, the Federal Food Drug and Cosmetic Act, and the National Environmental Protection Act, etc.) already speaking directly to the issue, the FDA was left with limited enforcement discretion.[125] Thus, the court's main objective became ensuring that the FDA's policy statement comported with Congressional directives.[126]

The plaintiff's contended that the FDA's policy statement was in fact *not* a statement of policy, but rather a substantive rule. Thus, it was improper for the FDA to issue its policy without a formal notice and comment process.[127] As to this issue, the court held that "[a]lthough the distinction between these categories is not entirely clear," the court would use a two-part test for determining the difference between a substantive rule and a policy statement.[128] "A policy statement 1.) must not impose any new rights or obligations,

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[122] *Id.* at 170.

[123] *Id.*

[124] *Id.* at 171.

[125] *Id.*

[126] *Id.* at 171-72.

[127] *Id.*

[128] *Id.*

and 2.) must 'genuinely leave the agency and its decision-makers free to exercise discretion. . . . '[T]he ultimate issue is the agency's intent to be bound.'"[129] The court noted that the FDA named the measure at issue a "policy statement," and that the statement does not have a binding effect.[130] The court noted that the FDA's announcement that transferred genetic material is presumed to be generally regarded as safe ("GRAS"), is just that–a rebuttable presumption.[131] In fact, divergent views have been expressed concerning the scientific legitimacy of this policy.[132] "Rebuttable presumptions leave an agency free to exercise its discretion and may therefore properly be announced in policy statements."[133] Thus, the FDA did not err it its choice of not employing notice-and-comment rulemaking.[134]

With regard to the claim that the FDA was in violation of the NEPA by failing to perform an environmental assessment or an environmental impact statement, the court held that "[i]f the agency is not engaging in a major federal action, NEPA requirements do not apply . . . Agencies enjoy wide discretion in interpreting regulations, and the agency's interpretation will be upheld unless it is arbitrary and capricious."[135] The court continued on to state, "While declaring a rebuttable presumption that foods produced through rDNA technology are GRAS, the FDA has neither made a final determination that any particular food will be allowed into the environment, nor taken any particular regulatory actions that could affect the environment."[136] The court also noted that the FDA's policy statement had not altered the status quo because "rDNA modified foods . . . were regulated no differently before the publication of the Policy Statement than they are now . . . [thus] it is not a major federal

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129 *Id.*

130 *Id.*

131 *Id.*

132 *See* Pelletier, *supra* note 53.

133 *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 172.

134 *Id.* at 173.

135 *Id.* at 174.

136 *Id.*

action."[137] The court also stated that NEPA only applies to agency actions "even if inaction has environmental consequences."[138] Because the FDA had merely announced a presumption and had taken no overt action, the FDA's presumption was therefore not subject to NEPA requirements.[139]

Under the FDCA, any substance which may "becom[e] a component or otherwise affect . . . the characteristics of any food" should be deemed a food additive.[140] The court noted that the FDA reasoned that the "only substances added to rDNA engineered foods are nucleic acid proteins."[141] Because "nucleic acids are present in the cells of every living organism, [they] do not raise a safety concern as a component of food."[142] Thus, the court found that the FDA correctly concluded that rDNA processed foods were presumed to be GRAS.[143]

In making their determination, the court applied *Chevron* analysis.[144] In the first step of the analysis, the court determined that Congress had spoken directly to the issue at hand. Because the court answered this in the affirmative, "that is the end of the matter . . . for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[145] Applying the second step of the *Chevron* analysis, the court focused on "discerning the boundaries of Congress' delegation of authority to the agency."[146] In resolving this issue, the court looked at "whether the agency's construction of the statute is faithful to its plain meaning, or if the statute has no plain meaning, whether the agency's interpretation 'is based on a permissible construction of the statute.'"[147] The court

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137 *Id.*

138 *Id.* at 174-75.

139 *Id.* at 175.

140 21 U.S.C. § 321(s).

141 *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 176.

142 *Id.*

143 *Id.*

144 Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

145 *Id.*

146 *Id.*

147 *Id.*

decided that though "food additive" as defined by § 321(s) was intended to have a broad meaning, "the statute exempts from regulation . . . substances that are 'generally recognized . . . to be safe under the conditions of its intended use.'"[148] Because the plaintiffs had not disputed that nucleic acid proteins themselves are generally recognized as safe, the court deferred to the agency on this issue.[149] The court noted that, "in an area characterized by scientific and technological uncertainty[,] . . . this court must proceed with particular caution, avoiding all temptation to direct the agency in a choice between rational alternatives."[150]

In assessing safety, a substance must meet the following two criteria: "1) it must have technical evidence of safety, usually derived from published scientific studies; and 2) the technical evidence must be generally known and accepted in the scientific community.[151] Though the plaintiffs produced several documents showing significant disagreement among scientists regarding the safety of genetically engineered food, the court was bound to confine its review to the record that was before the agency at the time of its decision and could not take any information to the contrary into account.[152]

In light of the United States District court's careful consideration of the characterization of a policy statement, whether or not Congress has directly spoken to the issue, and the scientific knowledge that has developed since the FDA issued its policy statement, it is now more important than ever for Congress to speak directly with regard to strengthening the regulations and labeling requirements of genetically modified foods.

A. Lack of Studies

The lack of studies showing true safety of GM food consumption is a problem, which needs to be addressed on behalf of the American

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148 *Id.*

149 *Id.* at 177.

150 *Id.*

151 *Id.*

152 *Id.*

people. Sources confirm that a scientific basis does exist with respect to the possibility that genetic engineering could create food safety problems, and current testing methods are inadequate in many ways.[153] With regard to the FDA's policy statement, FDA microbiologist Dr. Louis Pribyl expressed the following concern: "What has happened to the scientific elements . . . . The unintended effects cannot be written off so easily by just implying that they too occur in traditional breeding . . . . It is not prudent to rely on plant breeders always finding these types of changes . . . . Nowhere is such an issue discussed or examined in this document.[154] The Director of the FDA's Center of Veterinary Medicine, Dr. Gerald Guest, wrote in a February 5th, 1992 memo: "In response to your question on how the agency should regulate genetically modified food plants, I . . . have concluded that there is ample scientific justification to support a pre-market review of these products . . . I would urge you to eliminate statements that suggest that the lack of information can be used as evidence for no regulatory concerns."[155]

The Rowett Institute in Aberdeen, Scotland is one of the world's leading nutritional institutes.[156] Known for being thorough throughout his career, the Rowett institute is where the esteemed Dr. Arpad Pusztai worked as a researcher.[157] He has published nearly 300 scientific articles, authored or edited twelve books, and frequently collaborated with top researchers from around the world.[158] Arpad's wife Susan was also a distinguished senior scientist, and a colleague at the Rowett Institute. In 1995, Pusztai was chosen as coordinator of a research consortium that was awarded a £1.6 million grant to create a model to test genetically modified foods–verifying they were safe for consumption.[159] The consortium's testing methods would later

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153 Pelletier, *supra* note 53 at 210-11.

154 *Id.* at 212.

155 *Id.*

156 JEFFREY M. SMITH, SEEDS OF DECEPTION: EXPOSING INDUSTRY AND GOVERNMENT LIES ABOUT THE SAFETY OF THE GENETICALLY ENGINEERED FOODS YOU'RE EATING 5 (Yes! Books ed. 6th prtg., 2003).

157 *Id.* at 7.

158 *Id.*

159 *Id.*

become the standard used in Britain and throughout the European Union.[160] As the world's expert on lectins, Pustzai spent nearly seven years researching a lectin's properties, which he knew was safe for human consumption.[161] Before conducting his study with the GM lectin potatoes, Pustzai conducted a previous study where he fed rats the equivalent of 800 times the amount of lectins he would be introducing into the GM potato, with no apparent damage to the rats.[162] Thus, this particular lectin, in and of itself was proven harmless.[163] In deciding to use a GM potato with this lectin, Pusztai was not expecting any adverse effects on the rats.[164]

There were three groups of rats: 1) rats who were fed GM potatoes, 2) rats who were fed natural potatoes, and 3) rats who were fed natural potatoes that were spiked with the same amount of pure lectin that was found in the GM potato.[165] The researchers varied the preparation of the potatoes between raw, boiled, and baked.[166] The total protein content of the rats' diets also varied tested at both 10-day and 110-day periods.[167] The testing protocol used had been thoroughly scrutinized and approved in advance by the government's funding office, and was consistent with several published studies.[168] What Pusztai found was shocking. Even though the GM potato and non-GM parent lines were grown in identical conditions, the nutritional content of some GM potatoes were found to be considerably different.[169] Pusztai found that the rats fed with GM potatoes suffered damage to their immune systems.[170] Their white blood cells responded more sluggishly than those fed the non-

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160 *Id.*

161 *Id.* at 11.

162 *Id.*

163 *Id.* at 11.

164 *Id.*

165 *Id.* at 12.

166 *Id.*

167 *Id.* at 12.

168 *Id.* at 12-13.

169 *Id.* at 11-12.

170 *Id.* at 12.

GM potatoes.[171] Thus, these rats were more vulnerable to disease and infection.[172] The thymus and the spleen of the rats that were fed the GM potatoes were also damaged.[173] As compared with the rats which were fed the non-GM potatoes, the GM potato fed rats had enlarged tissues, including their pancreas and their intestines.[174] "Some of these rats also showed partial liver atrophy."[175] Structural changes were also identified in the cells of the stomach and intestines of the GM-fed rats, signaling the possibility that those rats may have an increased potential for cancer.[176]

Only the rats who ate GM potatoes suffered serious negative side effects.[177] Due to his knowledge from his previous research and the data from this study, it was clear that it was not the lectin that caused the major health damage, but the process of genetic engineering itself.[178] Pustzai said, "We used exactly the same methods of genetic engineering as used by the food companies. . . . [These] facts indicated to me there were serious problems with transgenic food.[179] "It can take two to three years to get science papers published and these foods were already on the shelves without rigorous biological testing similar to that of our GM potato work."[180] As Pusztai's concerns for the public were mounting, he was approached by the British TV show, World in Action.[181] The show knew Pustzai's team was the only one in the world who was conducting thorough feeding research trials on GM foods.[182] Traditionally, scientists remain silent on their research until their findings can be presented at a conference

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171 *Id.*

172 *Id.*

173 *Id.*

174 *Id.*

175 *Id.*

176 *Id.*

177 *Id.* at 13.

178 *Id.*

179 *Id.*

180 *Id.*

181 *Id.* at 13-14.

182 *Id.* at 14.

or through a publication.[183] However, out of public concern, Pusztai decided he should warn the public of his findings immediately, especially considering the research was funded by British taxpayers.[184] With approval from the director of the Rowett Institute, Professor Phillip James, Pusztai conducted the interview and James sent along the institute's public relations officer for the taping.[185] During the interview, Pusztai said that more safety research was needed on this topic and that if he were given the choice, "[he] wouldn't eat it."[186] This sounded an immediate alarm with consumers and attracted a great deal of attention.[187]

By the time Pustzai showed up for work, he was bombarded with so many questions from the press that his phones were shut down, and all incoming press inquiries were then directed to James.[188] James began issuing press releases without first fact checking or discussing their content with Pustzai or anyone on the research team.[189] Unfortunately, the information disseminated by James was incorrect, including the type of lectin that was used.[190] James said Pustzai used the concavalin A lectin which is a known toxic immune suppressant, when the lectin actually used by Pustzai was from the snowdrop plant called GNA and is known to be completely harmless to both rats and humans.[191] James' mistake had completely confused and misled the public.[192] Together, the Pustzais set up a meeting with James to explain the mistake and misinformation he was providing.[193] James acknowledged the mistake and agreed to attempt to reverse it

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183 *Id.*

184 *Id.*

185 *Id.*

186 Martin Enserink, *Institute Copes with Genetic Hot Potato*, 281 SCIENCE 1124 (1998).

187 *Id.* at 1125.

188 SMITH, *supra* note 155 at 16.

189 *Id.*

190 *Id.* at 16-17.

191 *Id.* at 17.

192 *Id.*

193 *Id.*

with the correct information.[194] However, when Pustzai returned to work the next day, he was told he was suspended and forced to retire.[195] The research team's computers were blocked, and all data, and research notes related to his GMO experiments were confiscated.[196] Pustzai realized that James' decisions may have been compromised by political interference, as Tony Blair was a supporter of the biotech industry and James may have been in the running to be the primary candidate to head up a major government office under Blair's administration.[197]

The suspension of Pustzai allowed James to retain his credibility because it permitted James to refrain from admitting that he had been disseminating false information.[198] James then invoked a clause in Pusztai's contract, forbidding Pusztai from "say[ing] anything to anyone without the written permission of the director."[199] During this time, James was free to disparage Pustzai's reputation and challenge his methods used to undermine the results of the study by challenging his methods.[200] Later it was learned that Monsanto gave the Rowett Institute £140,000.[201] Parliament requested that Pusztai present his evidence before the Science and Technology Committee of the House of Commons.[202] This request overrode the silence clause of Pusztai's contract with Rowett and Pusztai was free to speak on the matter for the first time.[203] Pustzai and his partner Ewen responded to the criticism of their study in the Lancet:

> It beggars [sic] belief that 'badly designed, poorly carried out, inaccurately interpreted experiments' could have perpetuated such profound public debate for almost a year. . . . [N]ot all the facts were in

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194 *Id.* at 18.

195 *Id.*

196 *Id.*

197 *Id.* at 19.

198 *Id.*

199 *Id.* at 20.

200 *See id.* at 21.

201 *Id.* at 23.

202 *Id.*

203 *Id.*

> the possession of the Royal Society. Thus, it is difficult to understand how they could deduce that the experiments were 'badly designed and poorly carried out' from an internal report . . . that contained no such details. . . . The unsolicited report of the Royal Society, produced by clandestine 'peer review', is depreciable, because . . . committees are redolent with advisers linked to biotechnology companies. . . . It would be helpful if . . . authoritative opinions were supported by published results of biological, nutritional, and immunological testing with mammals before introduction into the human diet. . . . [O]ther equally valid opinions do not agree with the view that the GM route is the only salvation for mankind. . . . [N]obody can be completely certain whether or not they have consumed GM foods and overseas consumers cannot be declared unaffected until chronic symptoms are identified, collated, and published.[204]

In 2005, Pustzai received the Whistleblower Award from the German section of the International Association of Lawyers Against Nuclear Arms and the Federation of German Scientists.[205] In 2009, Pusztai and his wife Susan received the Stuttgart peace prize.[206]

In 2012, French scientists released the results of the first two-year study of Roundup herbicide toxicity and Roundup-tolerant genetically modified maize.[207] At the time of publication, this study used the highest number of rats regularly measured in a standard GMO diet study.[208] However, in an unprecedented fashion, an in violation of the guidelines of the Committee on Publication Ethics (COPE), this study was later retracted for "inconclusiveness."[209] The

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[204] Stanley W. B. Ewen & Arpad Pusztai, *Health Risks of Genetically Modified Foods*, 354 THE LANCET 684, 684 (1999).

[205] Federation of German Scientists, *Award Laureates*, http://www.cbd.int/doc/external/mop-04/fgs-1-en.pdf (last visited Nov. 16, 2013).

[206] N.J. Jaeger, *Global to Local: Stuttgart Peace Prize Honors GMO Whistleblowers*, EXAMINER.COM (Dec. 11, 2009), http://www.examiner.com/article/global-to-local-stuttgart-peace-prize-honors-gmo-whistleblowers.

[207] Gilles-Eric Séralini et al., *Long Term Toxicity of A Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize*, 50 FOOD & CHEM. TOXICOLOGY 4221, 4221 (2012). Retracted 63 Food & Chem. Toxicology 244 (2014).

[208] *Id.* at 4222.

[209] "Your decision to retract . . . is in clear violation of the international ethical norms as laid down by the Committee on Publication Ethics, of which Food and Chemical Toxicology is a member. According to COPE, the only grounds for retraction are clear evidence that the findings are unreliable due to misconduct or honest error; plagiarism or redundant publication; or unethical research. You have already acknowledged that the paper contains none of those faults. This arbitrary, groundless retraction of a published, thoroughly peer-

study was designed to evaluate the potential health effects of direct or indirect consequences of genetic modification itself from GM maize (Monsanto's Roundup tolerant NK603) consumption, the formulated herbicide mixture that is used on the genetically modified corn (Roundup), and the combination of both used together.[210] Virgin albino Sprague-Dawley rats were used as mammalian subjects.[211]

Though the original study was retracted, due to the overall lack of pertinent research on this subject matter, the findings of the study are still worthy of discussion. Two types of maize were used.[212] One was genetically modified R-tolerant NK603 by Monsanto.[213] The control corn was the nearest isogenic non-transgenic maize.[214] One field of NK603 was treated with Roundup, while the other NK603 field was left untreated.[215] Dry rat feed was then created containing 11%, 22%, or 33% concentrations of both types of maize.[216] Roundup was also tested in the rat's drinking water by itself at environmentally relevant low doses, which started below the range of levels permitted by regulatory authorities in drinking water.[217] The study's results were shocking. Between 50% and 80% of female rats developed large tumors by the 24th month, while only 30% of the control rats developed tumors.[218] Up to 70% of the female rats died

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reviewed paper is without precedent in the history of scientific publishing and raises grave concerns about the integrity and impartiality of science." Henry A Becker et al., *Reaping the whirlwind*, TIMES HIGHER EDUCATION (May 23, 2014, 7:09 AM), http://www.timeshighereducation.co.uk/comment/letters/reaping-the-whirlwind/2009936.article. "Seralini and his team stand by their results, and allege that the retraction derives from the journal's editorial appointment of biologist Richard Goodman, who previously worked for biology giant Monsanto for seven years." *Study Linking Genetically Modified Corn to Rat Tumors is Retracted*, SCIENTIFIC AMERICAN (Feb. 21, 2014, 4:17 PM), http://www.scientificamerican.com/article/study-linking-genetically-modified-corn-to-cancer/.

210 *Id.* at 4222.

211 *Id.* at 4223.

212 *Id.* at 4222.

213 *Id.*

214 *Id.*

215 *Id.*

216 *Id.*

217 *Id.* at 4223.

218 *Id.* at 4222.

prematurely, while only 20% of females prematurely died in the control group.[219] The tumors found in the rats that were fed genetically modified corn were between two to three times larger than in the control group.[220] Just as with the Pustazi study, wide criticism arose regarding Seralini's results. The European Food Safety Authority (EFSA) reviewed Seralini's data and concluded that the small differences detected were within the normal range for control rats.[221] The EFSA also criticized Seralini's statistical methodology.[222] The Food Standards Australia New Zealand (FSANZ), a panel of independent toxicologists funded by Monsanto, also supported the EFSA's conclusions.[223]

Dr. Doug Gurian-Sherman is a scientist who served on an FDA biotech advisory committee from 2002 to 2005.[224] Gurian-Sherman said, "We simply aren't doing the kinds of tests we need to do to have confidence in the safety of these crops."[225] On the day the findings of Seralini's study were published in the International Journal of Biological Sciences, Monsanto shares dropped 3%.[226] Monsanto's reaction was to reiterate its mantra that its products are well tested and safe.[227] Monsanto, claimed the study was based on "unsubstantiated conclusions", and promptly attempted to dismiss

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[219] *Id.* at 4224.

[220] *Id.* at 4223.

[221] *Statement of the Scientific Panel on Genetically Modified Organisms on the Analysis of Data from a 90-Day Rat Feeding Study with MON 863 Maize*, EUROPEAN FOOD SAFETY AUTHORITY (June 25, 2007), http://www.efsa.europa.eu/en/efsajournal/doc/753.pdf.

[222] EFSA REVIEW OF STATISTICAL ANALYSIS CONDUCTED FOR THE ASSESSMENT OF THE MON 863 90-DAY RAT FEEDING STUDY, EUROPEAN FOOD SAFETY AUTHORITY (June 2007), http://dx.doi.org/10.2903%2Fj.efsa.2007.19r.htm.

[223] J. Doull et al., *Report of an Expert Panel on the Reanalysis by Seralini et al. (2007) of a 90-Day Study Conducted by Monsanto in Support of the Safety of a Genetically Modified Corn Variety (MON 863)*, 45 FOOD AND CHEM. TOXICOLOGY 2073, 2084 (2007).

[224] Carey Gillam, *Mainstream Science Questions GMO Safety and Lack of Testing*, REUTERS (Apr. 14, 2010, 11:24 PM), http://laudyms.wordpress.com/2010/04/14/mainstream-science-questions-gmo-safety-and-lack-of-testing/.

[225] *Id.*

[226] *Id.* at 3.

[227] *Id.*

it.[228] Compounding the biotech industry's pushback against the calling for increased GMO studies and testing is the fact that biotech corporation's own the intellectual property of their genetic alterations. With patents in hand, biotech companies are perfectly within their legal right to bar outsiders from testing their GM seeds without company approval.[229]

V. AMERICANS TAKE ACTION

Though it has not yet been pursued, part of President Barack Obama's policy platform is the mandatory labeling of any food product containing a genetically engineered ingredient.[230] Fed up with the inadequacies of the current federal regulation structure, states are beginning to take matters into their own hands on behalf of their concerned citizens. The state of Vermont attempted to pass a bill requiring labels on all genetically modified food.[231] However, despite having passed the Vermont House Committee for Agriculture by a nine to one vote, the bill did not become law due to the threat of a costly lawsuit from Monsanto.[232]

Similarly, California attempted to take up a GMO labeling measure. Despite overwhelming initial public support for the proposition, California's Proposition 37 did not pass. Contributing to its demise was the fact that the bill's opponents out funded its proponents by an eight to one margin. A list of top financial contributors in support of Proposition 37 included Clif Bar & Company, Amy's Kitchen, the Organic Consumers Association, Dr. Bronner's Magic Soaps, and the Organic Consumers Fund.[233] The

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[228] *Id.*

[229] *Id.*

[230] Glenn G. Lammi, *Mandatory Labeling of Genetically Enhanced Foods: Why It's Not On the Policy Menu*, FORBES (Feb. 22, 2011), http://www.forbes.com/sites/docket/2011/02/22/mandatory-labeling-of-genetically-enhanced-foods-why-its-not-on-the-policy-menu/.

[231] *See* 112 CONG. REC. S4169 (daily ed. June 14, 2012) (statement of Sen. Sanders).

[232] *Id.*

[233] *Who's Funding Prop 37, Labeling for Genetically Engineered Foods?*, KCET PRESENTS ELECTION 2012 (Nov. 14, 2012), *available at*

largest opponents of Proposition 37 included pesticide, chemical, and biotechnology corporations such as Monsanto, Dupont, Bayer, and Dow, and food giants such as General Mills and Del Monte Foods Company.[234]

Few were surprised when it emerged that the state of California would be the first to tackle a proposition of this kind. California remained the number one state in cash farm receipts in 2010.[235] Its $37.5 billion in revenue represents 11.9 percent of the United States total.[236] Overall, California accounted for 16% of national receipts for crops, and 7% of the U.S. revenue for livestock and livestock products.[237] California's agricultural abundance includes more than 400 commodities while the state produces nearly half of U.S.-grown fruits, nuts, and vegetables.[238] To date, no state has been able to successfully enact a GMO labeling requirement.[239]

A. Pending Federal Legislation

Currently, there is a regulation proposed at the federal level by Representative Dennis Kucinich.[240] H.R. 3553 is a comprehensive bill requiring labels on all GMO foods or foods processed using GMO ingredients.[241] In the findings section of this proposed legislation, Congress recognizes that genetic engineering of foods does in fact result in a material change of such foods.[242] The bill states that mandatory labeling would provide for continual post market surveillance to study the long-term health impacts and enforcement of food safety laws that are designed to prevent adulterated foods

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http://www.kcet.org/news/ballotbrief/elections2012/propositions/prop-37-funding-genetically-engineered-food.html.

234 *Id.*

235 CAL. DEP'T OF FOOD & AGRIC., CALIFORNIA AGRICULTURAL STATISTICS REVIEW 2011-2012 2, (2012). http://www.cdfa.ca.gov/Statistics/PDFs/ResourceDirectory_2011-2012.pdf.

236 *Id.*

237 *Id.*

238 *Id.*

239 *See* Fredland, *supra* note 40, at 189.

240 H.R. 3553, 112th Cong. (2011).

241 *Id.*

242 *Id.* at § 2(1).

from reaching American consumers.[243] The bill also recognizes that many of our "key trading partners, including countries in the European Union, Japan, and the People's Republic of China, have established, or are in the process of implementing mandatory labeling requirements for genetically engineered foods."[244] The required notices proposed by this bill would be either "GENETICALLY ENGINEERED" or "THIS PRODUCT CONTAINS A GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL." The bill defines "genetically engineered material" as material derived from any part of a genetically engineered organism, without regard to whether the altered molecular or cellular characteristics of the organism are detectable in the material.[245] "Genetically engineered organism" is defined as:

> an organism (including fish) that has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes (including but not limited to rDNA and RNA techniques, cell fusion, microencapsulation, gene deletion and doubling, introducing a foreign gene, and changing the position of genes), other than a means consisting exclusively of breeding conjugation, fermentation, hybridization, in vitro fertilization, tissue culture, or mutagenesis.[246]

This comprehensive bill also addresses food chain issues by covering animals that have been fed genetically engineered material.[247] The periodic testing of foods will be mandated to ensure the accuracy of labels.[248] The "best available technology" would also be required to perform such testing.[249]

Ensuring that the bill's contents are feasible in application, the food does not have to contain a "genetically engineered material" label if it is found through testing that it does not contain any

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[243] *Id.* at § 2(7).

[244] *Id.* at § 2(8).

[245] *Id.* at § 3(a)(2)(A).

[246] *Id.* at § 3(a)(3)(A).

[247] *Id.* at § 3(a)(3)(B).

[248] *Id.* at § 3(a)(5).

[249] *Id.*

genetically engineered material, or if the amount of genetically engineered material found is one percent or less.[250] There is also a provision to lower the one percent threshold maximum if the Secretary determines that technology is capable of enhanced testing that can detect a percentage smaller than one percent.[251] The penalties for violating this labeling law can reach up to $100,000 for every violation.[252] There is also a provision that protects manufacturers or sellers that may be found to be in violation of this law, but still acted in good faith. Good faith can be established if the recipient of the food shows a guaranty or undertaking that the food does not contain and was not produced with genetically engineered material.[253] The guaranty or undertaking must also include the name, address, and signature of the person in the U.S. from whom he received the food; including the receipt of seeds to grow raw agricultural commodities.[254] This measure protects honest manufacturers from any unintended contamination that may take place in the transport or manufacturing process of foods. Though it remains to be seen whether this bill will stand the test of time, history has shown that when a legal loophole exists, an opportunistic many eagerly awaits to push money through it. Unfortunately for Americans, those profits may be coming at the expense of their health.

Congressman Kucinich is not the only American politician concerned with America's lack of genetically modified food labeling regulations. Senators Boxer and Sanders tried their hands at a GMO labeling provision as well.[255] Speaking for their Amendment No. 2310, Senator Sanders took to the Senate floor to garner support for their legislation. Senator Sanders said:

> [P]eople are becoming more and more conscious about the foods they are eating and the foods they are serving to their kids. . . . [I]t is a major concern all over our country. . . . We want to know what is in the food we are eating and whether that food is genetically engineered. . . .

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250 *Id.* at § 3(a)(6).

251 *Id.*

252 *Id.* at § 3(b).

253 *Id.*

254 *Id.* at § 3(c).

255 S. Amendment 2310, 112th Cong. (2012).

> According to an MSNBC poll in February of 2011, 95 percent of Americans agree that labeling of food with genetically engineered ingredients should be allowed. . . . Monsanto . . . does not like this idea. . . . Monsanto is also the world's largest producer of the herbicide Roundup, as well as so-called Roundup Ready seeds that have been genetically engineered to resist the pesticide. . . . This amendment recognizes that the 10th amendment to the U.S. Constitution clearly reserves powers in our system of federalism to the States and to the people. . . There are strong precedents for labeling. . . . If we want to know if our food contains gluten, aspartame, high-fructose corn syrup, trans fats or MSG, we simply read the label. . . . [T]he FDA requires labeling for major food allergens such as peanuts, wheat, shellfish, and others. But Americans for some reason, are not afforded that same information when it comes to genetically engineered foods. . . . Genetically engineered foods are already required to be labeled in 49 countries around the world. . .[but] [w]e have a large, powerful, multinational corporation that is more concerned about their own profits than they are about allowing the American people to know what is in the food they are eating. . . . [T]here have never been mandatory human clinical trials of genetically engineered crops – not tests for the possibility of it causing cancer or for harm to fetuses, no long-term testing for human health risks, no requirement for long-term testing on animals, and only limited allergy testing. . . . [T]he long-term health study on GE food is being done on the American people. We are the clinical test.[256]

B. Potential Constitutional Challenge

Should Dennis Kucinich's bill pass, or the FDA act independently to require the labeling of genetically modified foods, there are many cases showing that there would be much debate about whether these labeling requirements are constitutional under the First Amendment in the commercial speech context. In *Thompson v. Western States Medical Center*,[257] and 44 *Liquormart, Inc. v. Rhode Island*,[258] the Supreme Court ruled that commercial speech is protected. Compelled speech is subjected to the same level of scrutiny as restricted speech, especially when the compelled speech may force companies to make statements they may not agree with or

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[256] *Id.*

[257] 535 U.S. 357 (2002) (striking down a federal prohibition on the advertising of certain compounded drugs).

[258] 517 U.S. 484 (1996) (striking down a state ban on the advertising of prescription drug prices).

that may be confusing.[259] There are generally two tests used for First Amendment commercial speech analysis. Under the *Central Hudson* test,[260] the commercial speech analysis is first concerned with whether or not there is a need to protect the public from information that may be misleading.[261] Under the *Zauderer* standard, [262] a compelled disclosure of "purely factual and uncontroversial information" is constitutional if it is "reasonably related to the state's interest in preventing" deception of the consumer because the restriction would not be "unjustified or unduly burdensome" under the First Amendment.[263]

1. The Popular "Analogous" Issue

When California's Proposition 37 garnered so much momentum that it looked like it would pass, panic and fear ensued in the biotech community. Legal teams began postulating preemptively about the various ways Proposition 37 could be invalidated were it to pass. One often heard argument against Proposition 37, uses a semi-analogous issue – rBGH and the first Amendment issues raised in *International Dairy Foods Association v. Amestoy*.[264]

rBGH is a recombinant bovine growth hormone that is used by dairy farmers to increase a cow's milk production. The Monsanto Company is the manufacturer of the rBGH drug Posilac.[265] Monsanto applied for approval of Posilac in 1987.[266] Thousands of letters were sent to the FDA from concerned consumers seeking the denial of

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[259] *See United States v. United Foods*, 533 U.S. 405 (2001) ("Just as the First Amendment may prevent the government from prohibiting speech, the Amendment may prevent the government from compelling individuals to express certain views").

[260] Central Hudson Gas & Electric Corp. v. Public Survice Commission, 447 U.S. 557 (1980).

[261] Jonathan Adler, *Regulating Genetically Modified Foods: Is Mandatory Labeling The Right Answer?*, 10 RICH. J.L. & TECH. 14 (2004).

[262] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

[263] *Id.*

[264] Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996).

[265] Andrew J. Nicholas, *As the Organic Food Industry Gets Its House in Order, the Time Has Come for National Standards for Genetically Modified Foods*, 15 LOY. CONSUMER L. REV. 277, 290 (2003).

[266] *Id.*

Posilac's approval, or the requirement of a label for dairy products containing milk from cows treated with Posilac.[267] Despite vocal skepticism and concern from scientists, farmers, and environmental groups, Posilac was approved by the FDA in November of 1993.[268] The FDA's approval decision was based on information supplied to the FDA by Monsanto itself.[269] The FDA concluded that there was no difference between the milk of untreated cows and milk from cows treated with Posilac.[270] In the past, based on the information received by Monsanto, the FDA believed that dairy milk produced by cows that were exposed to rBGH was indistinguishable from the milk of untreated herds.[271] As science has caught up with technology, we now know that rBGH increases levels of insulin like growth factor (IGF-1) in milk.[272]

Studies have shown that increased IGF-1 levels are a risk factor for multiple types of cancer including colorectal cancer, prostate cancer, and breast cancer.[273] Dr. Edward Giovannucci, an assistant professor at Harvard explained:

> When IGF-1 is added to dishes of cells growing in the laboratory, the cells flourish like flowers blooming in spring. In children, the hormone stimulates bone growth and development of organs such as the heart, liver, and kidneys. But in older people, rapidly proliferating cells increase the opportunity for genetic mutations that may lead to cancer. And once cancer cells begin to form, IGF-1 will promote their growth as well as that of normal cells.[274]

2. *Similar Challenges*

It is important to remain cognizant of how the past relates to the

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[267] *Id.*

[268] *Id.*

[269] *Id.*

[270] *Id.*

[271] *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 69 (2d Cir. 1996).

[272] Colin G. Prosser et al., *Increased secretion of insulin-like growth factor I into milk of cows treated with recombinantly derived bovine growth hormone*, 56 J. OF DAIRY RES. 17, 17-26 (1989).

[273] Gregor Fürstenberger, *Insulin-like growth factors and cancer*, 3 THE LANCET ONCOLOGY 298, 298-302 (2002).

[274] William J. Cromie, *Growth Factor Raises Cancer Risk*, HARVARD UNIV. GAZETTE (April 22, 1999), http://www.news.harvard.edu/gazette/1999/04.22/igf1.story.html

present because of cases like *Amestoy*[275] and *Stauber v. Shalala*.[276] In *Stauber*, consumers filed suit challenging the FDA on both its approval of Posilac and its refusal to require a label for dairy products that were treated with Posilac.[277] This case is a classic example of how the FDA performs its regulatory duty and the way citizens' attempts at recourse are often futile. The court held that as long as the FDA had taken into account relevant factors, and the court could find a rational basis for the agency's decision, then the FDA's decision would be upheld.[278] The opinion states that before Posilac's approval, the FDA reviewed data submitted by Monsanto as part of its application for approval.[279] The court noted that a Monsanto sponsored two-week study of rats indicating no adverse effects was sufficient to support a finding that the FDA's approval decision was not arbitrary and capricious, even though the plaintiffs had valid concerns regarding the use of Posilac.[280] The opinion states:

> At the time Monsanto filed its new drug application for Posilac, not much was known about the hormone. Defendants have done no long term studies on the effects of increased levels of IGF-1 on human health . . . . On the basis of . . . the data submitted by Monsanto, the FDA concluded that there is no significant difference between milk from cows treated with Posilac and milk from untreated cows."[281] Posilac was also approved without the preparation of an environmental impact statement with regard to the National Environmental Policy Act.[282] "The FDA based this conclusion on an environmental assessment prepared by Monsanto.[283]

The National Environmental Policy Act of 1970 (NEPA) requires federal agencies to evaluate potential environmental impacts prior to taking certain actions or making certain decisions that could

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275 92 F.3d at 69.

276 895 F. Supp. 1178 (W.D. Wis. 1995).

277 *Id.* at 1182.

278 *Id.*

279 *Id.* at 1184.

280 *Id.* at 1189.

281 *Id.* at 1185.

282 *Id.* at 1186.

283 *Id.*

potentiate environmental risk.[284] Each agency is to question whether its decision or action is likely to have significant environmental effects.[285] Furthermore, the FDA does not base its labeling decisions on consumer demand.[286] Americans should be concerned that the agency that is supposed to be protecting and controlling their future ability to seek and obtain recourse bases its decisions on information supplied from the very companies that are applying for approval. This does not seem like the most comprehensive, thoughtful approach to ensure the protection of the American food supply.

Subsequent to *Stauber*, two dairy companies started using labels on their milk indicating that it was milk from "untreated cows."[287] Monsanto sought an injunction against the companies–Swiss Valley Farms, Inc., and Pure Milk & Ice Cream Company, upon learning of the labels.[288] Monsanto claimed that the use of labels indicating "untreated cows" would somehow provide consumers with the impression that these firms' milk was somehow safer or of higher quality than the milk from treated cows.[289] Ultimately these did not go to trial, and their settlement agreements were never made public.[290] It is unknown whether the defendants were allowed to continue their use of "untreated cows" labeling.[291] Currently, many milk brands contain voluntary labels indicating the status of whether that product was made with dairy from cows treated with rBST. Through cases like these, Monsanto has consistently sent a clear message to any entity it views as in its way–label your product in a way that we view threatening, swift legal action will be taken against you. Cases like these are critical because Monsanto spent $300 million developing Posilac alone.[292]

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[284] McHugen & Smyth, *supra* note 2, at 6.

[285] *Id.*

[286] *Stauber*, 895 F.Supp. at 1193.

[287] Nicholas, supra note 261 at 294.

[288] *Id.*

[289] *Id.*

[290] *Id.*

[291] *Id.*

[292] *Id.* at 295.

At issue in *Amestoy* was the passage of a Vermont law requiring the labeling of products that came from cows treated with growth hormones. The Vermont labeling law required that "if rBST has been used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such."[293] Vermont's Commissioner of Agriculture then promulgated regulations that gave the dairy manufacturers four different labeling options from which to choose.[294] Dairy manufacturers filed suit alleging that the statute infringed upon their constitutionally protected First Amendment rights.[295] Because the dairy farmers did not want to use one of the four labels required by the legislation, the plaintiff's constitutional right *not* to speak was at issue.[296] It is worth noting that Monsanto acted as amicus in this action.[297] The dairy manufacturers argued that the speech required by the legislation was not purely commercial because it would compel them to convey a message that is expressly contrary to their views.[298] Under the standard argued by the dairy manufacturers in *Amestoy*, any legislation requiring the labeling of GMO food would not fit the same category. This is because a GMO label would be purely commercial speech–containing factual information that could in no way be contrary to any view of a food company.

The *Amestoy* court applied the *Central Hudson* test to analyze whether a government restriction on commercial speech is permissible.[299] The four *Central Hudson* factors are: 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.[300]

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293 *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 72 (2d Cir. 1996).

294 *Id.* at 69-70.

295 *Id.* at 70.

296 *Id.* at 71.

297 *Id.* at 72.

298 *Id.* at 71.

299 *Id.*

300 *Id.*

The court held that Vermont failed to establish the second prong of the test–requiring that the interest be substantial.[301] The court found that "strong consumer interest and the public's right to know" are insufficient to justify compromising protected constitutional rights.[302] It seems there is hope in the future for other labeling law provisions because though unaddressed by the court, the state of Vermont had other ways to successfully argue that they in fact did have a substantial interest in the law. If Vermont had advanced a more significant safety or public health purpose for their labeling requirement law, the court would likely have found the state did indeed have a substantial interest. One substantial interest would be to protect the farmers who choose not to use rBST on their cows. If rBST does its job by substantially increasing milk production and thus supply, then milk prices would then be reduced which could force the non-rBST farmers out of business due to the inability to produce economically sufficient milk volumes. Another substantial interest argument is to "worry about rBST's impact on human and cow health."[303] Invoking the First Amendment to invalidate a law that would simply require the disclosure of information to consumers is contrary to the policy of the First Amendment, which is to "favor the flow of accurate, relevant information" in a commercial context.[304]

With regard to the labeling of genetically modified foods, Vermont Representative Carolyn Partridge states, "It is hard to predict which test – *Zauderer* or *Central Hudson* – might be applied . . . We would rather not repeat the . . . *Amestoy* experience because it is expensive and if we were to lose, we would potentially pay for the winner's legal costs."[305] Currently no First Amendment labeling case has been tried at the Supreme Court level, leaving the door open to the possibility that with properly structured arguments and learning from key cases of the past, required GMO labeling may survive a

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[301] *Id.* at 73.

[302] *Id.* (quoting Int'l Dairy Food Ass'n v. Amestoy, 898 F. Supp. 246, 249 (D.Vt. 1995)).

[303] *Id.* at 74.

[304] *Id.*

[305] Rep. Carolyn Partridge: *The Complexities of Genetically Engineered Food Labeling* (Dec. 9, 2012, 10:30 AM), http://www.vthouse.org/blog/rep-carolyn-partridge-complexities-genetically-engineered-food-labeling.

First Amendment challenge.

VI. CONCLUSION

Since the "father of modern genetics" Gregor Mendel started his genetic experiments with garden peas, much has been discovered about how we can manipulate biology through technology. Genetic engineering technology has vastly expanded the types of foods made available to Americans. Over time we are learning more and more about the potential effects of these products. As Americans become increasingly aware of the role GMOs play in their lives, their voices of concern grow stronger, and scientific testing is slowly catching up with technology. There is much the United States can learn from the way other countries regulate GMO technology. It will be interesting to see the progression of this issue through both Congress and the judicial branch. Though it is clear that large biotech corporations would like to retain domination and control of their industry, more information is being disseminated which will likely impact the current ideology that governs the biotech industry. GMO labeling could bring us one step closer to ensuring the goals of the common good are being achieved for all Americans.